COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

Administered by

COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

ADHD AGE RESTRICTION OVERRIDE (ILLINOIS MEDICAID)

Generic	Brand	QL/Age	GPID
amphetamine sulfate tablets 5 mg, 10 mg	(Evekeo)		10 mg: 19821 5 mg: 19822
	DEXEDRINE SPANSULE ORAL CAPSULE, EXTENDED RELEASE 10 MG, 5 MG	QL (60 EA per 30 days); Age (Min 6 Years and Max 18 Years)	10 mg: 19850 5 mg: 19852
	DEXEDRINE SPANSULE ORAL CAPSULE, EXTENDED RELEASE 15 MG	QL (120 EA per 30 days); Age (Min 6 Years and Max 18 Years)	19851
dextroamphetamine oral tablet 10 mg	(Zenzedi)	QL (180 EA per 30 days); Age (Min 3 Years and Max 18 Years)	19880
dextroamphetamine oral tablet 5 mg	(Zenzedi)	QL (90 EA per 30 days); Age (Min 3 Years and Max 18 Years)	19881
dextroamphetamine-amphetamine oral capsule, extended release 24hr 10 mg, 15 mg, 5 mg	(Adderall XR)	QL (1 EA per 1 day); Age (Min 6 Years and Max 18 Years)	10 mg: 14635 15 mg: 17468 5 mg: 17459
dextroamphetamine-amphetamine oral capsule, extended release 24hr 20 mg, 25 mg, 30 mg	(Adderall XR)	QL (2 EA per 1 day); Age (Min 6 Years and Max 18 Years)	20 mg: 14636 25 mg: 17469 30 mg: 14637
dextroamphetamine-amphetamine oral tablet 10 mg, 12.5 mg, 15 mg, 20 mg, 30 mg, 5 mg, 7.5 mg	(Adderall)	QL (2 EA per 1 day); Age (Min 3 Years and Max 18 Years)	10 mg: 56971 12.5 mg: 29008 15 mg: 29009 20 mg: 56973 30 mg: 56972 5 mg: 56970 7.5 mg: 29007
DEXMETHYLPHENIDATE HCL	FOCALIN XR	QL (1 EA per 1 day)	5 mg: 24733 10 mg: 24734 20 mg: 24735 30 mg: 28035 40 mg: 28933 25 mg: 30305 35 mg: 30306 15 mg: 97111
methylphenidate ER 72 mg	RELEXXII	QL (1 EA per 1 day)	44239
	ZENZEDI ORAL TABLET 10 MG	QL (180 EA per 30 days); Age (Min 3 Years and Max 18 Years)	19880
	ZENZEDI ORAL TABLET 5 MG	QL (90 EA per 30 days);	19881

		Age (Min 3 Years and Max 18 Years)	
	ZENZEDI ORAL TABLET 2.5 MG, 7.5 MG, 15 MG, 20 MG		2.5 MG: 34734 7.5 MG: 34735 15 MG: 19885 20 MG: 36463
	ZENZEDI ORAL TABLET 30 MG	QL (2 EA per 1 day)	36464
	METADATE ER ORAL TABLET EXTENDED RELEASE 20 MG	QL (90 EA per 30 days); Age (Min 6 Years and Max 18 Years)	16180
methylphenidate hcl oral capsule, ER biphasic 30-70 10 mg, 20 mg, 40 mg, 50 mg, 60 mg		QL (1 EA per 1 day); Age (Min 6 Years and Max 18 Years)	20 mg: 13176 10 mg: 20384 40 mg: 26734 50 mg: 26735 60 mg: 26736
methylphenidate hcl oral capsule, ER biphasic 30-70 30 mg		QL (2 EA per 1 day); Age (Min 6 Years and Max 18 Years)	30 mg: 20386
methylphenidate hcl oral tablet 10 mg, 20 mg, 5 mg	(Ritalin)	QL (90 EA per 30 days); Age (Min 3 Years and Max 18 Years)	10 mg: 15911 20 mg: 15920 5 mg: 15913
methylphenidate hcl oral tablet extended release 10 mg		QL (3 EA per 1 day); Age (Min 6 Years and Max 18 Years)	93075
methylphenidate hcl oral tablet extended release 20 mg	(Metadate ER)	QL (90 EA per 30 days); Age (Min 6 Years and Max 18 Years)	16180
methylphenidate hcl oral tablet extended release 24hr 18 mg, 27 mg, 54 mg	(Concerta)	QL (1 EA per 1 day); Age (Min 6 Years and Max 18 Years)	18 mg: 12567 27 mg: 17123 54 mg: 12248
methylphenidate hcl oral tablet extended release 24hr 36 mg	(Concerta)	QL (2 EA per 1 day); Age (Min 6 Years and Max 18 Years)	12568

GUIDELINES FOR USE

1. Is the request for an age restriction override for a stimulant medication?

   If yes, continue to #2.
   If no, this guideline does not apply.

2. Is the request for a quantity limit override?

   If yes, please forward to Clinical for further review.
   If no, continue to #3.

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ADHD AGE RESTRICTION OVERRIDE (ILLINOIS MEDICAID)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD)?

   If yes, **approve for 12 months by GPID with quantity limits. Please enter the MDD (hard-coded quantity limit) for the requested medication per RL (restriction lookup).**
   If no, continue to #4.

4. Does the patient have a diagnosis of narcolepsy?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for methylphenidate 20mg ER tablet (Ritalin-SR, Metadate ER, Methylin ER), methylphenidate 10mg ER tablet (Methylin ER), amphetamine sulfate tablets (Evekeo), dextroamphetamine sulfate tablets (Dexedrine, Dextrostat, and Zenzedi), dextroamphetamine ER capsules (Dexedrine Spansule), or methylphenidate tablets (Ritalin and Methylin)?

   If yes, **approve for 12 months by GPID with quantity limits. Please enter the MDD (hard-coded quantity limit) for the requested medication per RL (restriction lookup).**
   If no, do not approve.
   DENIAL TEXT: This medication is available on the formulary for the treatment of Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) in patients who are age 18 years and older who have been receiving the medication as a pediatric patient. Additionally, Metadate ER, Ritalin-SR, Methylin ER, amphetamine sulfate tablets (Evekeo), dextroamphetamine sulfate tablets (Dexedrine, Dextrostat, and Zenzedi), dextroamphetamine ER capsules (Dexedrine Spansule), or methylphenidate tablets (Ritalin and Methylin) may be approved for the treatment of narcolepsy.

RATIONALE
Ensure appropriate use of CNS stimulants.

FDA APPROVED INDICATIONS
All medications on this guideline have FDA approval for ADHD. Metadate ER, Ritalin-SR, Methylin ER, Evekeo, Dexedrine, Dextrostat, Zenzedi, Dexedrine Spansule, Ritalin and Methylin have FDA approval for narcolepsy.

REFERENCES
- Micromedex Vol 126.
- Pliszka S. Practice parameter for the assessment and treatment of children and adolescents with attention deficit/hyperactivity disorder. J Am Acad Child Adolesc Psychiatry 2007; 46 (7): 894-921.

Created: 04/19
Effective: 03/09/20 Client Approval: 02/07/20 P&T Approval: N/A

COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

Cook County GENERAL FORMULARY EXCEPTION GUIDELINE

Note:

- **The CCX01 General Formulary Exception (FE) Guideline is used for drugs that reject either tier 2 or tier 5 or have a POS message of "NOT ON FORMULARY, PLEASE TRY FORMULARY MEDICATION OR SUBMIT A FORMULARY EXCEPTION REQUEST".**
- **Trial and failure in the context of this guideline can be interpreted as:**
  - **Allergy to preferred formulary medications available for the submitted indication**
  - **Contraindication to preferred formulary medications available for the submitted indication**
  - **History of unacceptable side effects to preferred formulary medications available for the submitted indication**
  - **Therapeutic failure with a trial of preferred formulary medications for the submitted indication**

Link to state PDL:
https://www.illinois.gov/hfs/MedicalProviders/Pharmacy/preferred/Pages/default.aspx

GUIDELINES FOR USE

INITIAL REQUESTS (NOTE: FOR RENEWAL REQUESTS SEE BELOW)

1. Is there a custom Cook County drug-specific guideline linked?

   If yes, GENERAL FORMULARY EXCEPTION GUIDELINE does not apply. Use custom guideline for review.
   If no, continue to #2.

2. Is the request for **continuation of care** for a drug that is within a CMS protected class and there is a MI standard guideline?
   CMS Protected classes include anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants.
   Note: Can accept statement on MRF that patient is stable on the drug

   If yes, review according to the Renewal Criteria within the MI guideline for the requested drug. Cite approval or denial based on guideline criteria.
   If no, continue to #3.

3. Is the request for **continuation of care** for a drug that is within a CMS protected class and there is **NOT** a MI standard guideline?
   CMS Protected classes include anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants.
   Note: Can accept statement on MRF that patient is stable on the drug

   If yes, approval up to 12 months by HICL based on formulary quantity limits.
   If no, continue to #4.

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Cook County GENERAL FORMULARY EXCEPTION GUIDELINE

INITIAL REQUESTS (CONTINUED)

4. Is the drug used to treat an urgent condition (Examples of urgent conditions include situations requiring anticoagulation, acute psychotic episodes, acute bleeding and neutropenia) **OR BOTH** of the following are met?
   - The patient is stable on regimen, **AND**
   - Disruption of treatment could result in harm to the patient including significant loss of function, hospitalization, or exacerbation

   If yes, **approve according to the limitations within the MI guideline or up to 12 months by HICL based on formulary quantity limits if guideline not available.**
   If no, continue to #5.

5. Is the drug being used for an FDA-approved (labeled) indication or if the drug is requested for a non-FDA approved indication, does the patient have a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in two peer-reviewed medical literature articles, accepted standards of medical practice, or in one of the following compendia?
   - American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use
   - Clinical Pharmacology: Contains narrative text supporting use
   - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A
   - Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb
   - Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: Use reason code G09.

6. Is the request for initial treatment with a CMS protected class including anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, or immunosuppressants **AND** there is a MI standard guideline?

   If yes, review according to the guideline. Cite approval or denial based on guideline criteria.
   If no, continue to #7.

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Cook County GENERAL FORMULARY EXCEPTION GUIDELINE

INITIAL REQUESTS (CONTINUED)

7. Is the request for initial treatment with a CMS protected class including anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, or immunosuppressants **AND** there is documentation from the prescriber of **AT LEAST ONE** of the following?
   a. A contraindication to preferred products pursuant to the pharmaceutical manufacturer's prescribing information **OR**
   b. Medical rationale that the requested product would be safer and/or more efficacious than using the formulary products **OR**
   c. Use of a preferred product could result in **ONE** of the following:
      i. An adverse reaction experienced by the patient,
      ii. Decreased ability of the patient to achieve or maintain reasonable functional ability in performing daily activities,
      iii. Cause physical or mental harm to the patient

   Note: Requests using criteria #7 should only be leveraged when there is a CMS protected class and no MI standard guideline.

   If yes, **approve up to 12 months by HICL based on formulary quantity limits if guideline not available.**
   If no, continue to #8.

8. Is the request for the initial treatment for a glucose monitor or test strip **AND** there is documentation from the prescriber of **AT LEAST ONE** of the following?
   a. A contraindication to a preferred glucose monitor or test strips pursuant to the pharmaceutical manufacturer's prescribing information **OR**
   b. Medical rationale that the requested glucose monitor or test strips would be safer and/or more efficacious than using the formulary products **OR**
   c. Patient uses an insulin pump (already approved) that requires use of a specific meter and test strips
   d. Use of a preferred product could result in **ONE** of the following:
      i. An adverse reaction experienced by the patient,
      ii. Decreased ability of the patient to achieve or maintain reasonable functional ability to do routine blood glucose testing and/or perform daily activities,
      iii. Cause physical or mental harm to the patient

   If the request is not for a glucose monitor or test strip, continue to #9.

   If yes, **approve up to 12 months and input authorizations for BOTH GPID 99994 for glucose meter and GPID 25200 for test strips based on formulary quantity limits.**
   If no, do not approve.
   DENIAL TEXT: Use reason code G09.

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Cook County GENERAL FORMULARY EXCEPTION GUIDELINE

INITIAL REQUESTS (CONTINUED)

9. Has the patient tried and failed **TWO** clinically appropriate formulary alternatives (if available) within that drug class for the requested indication?
   Note 1: If only one preferred formulary alternative is available within that same drug class, the patient is **ONLY** required to try and fail the **ONE** preferred formulary agent only.

   Note 2: If there are two clinically appropriate formulary alternatives **AND** the patient has tried and failed one preferred and one non-preferred agent within the same drug class and with the same indication, the non-preferred agent should be considered as meeting the requirement.

   Note 3: If there is a brand over generic strategy in place, follow standard FE process of requiring trial of 2 preferred agents within the same class. Trial of brand over the generic is not required to meet FE.

   Note 4: If the request is for a combo agent, the patient needs to try 2 PDL drugs that represent the same classes included in the combo product for approval (for example: ICS+LABA). If there are no preferred combo agents, the trial of preferred single agents within the drug class and indicated for the specified indication can be accepted.

   If yes, **approve according to the limitations within the MI guideline or up to 12 months by HICL based on formulary quantity limits if guideline not available.**

   If there are no preferred formulary alternatives for the specified indication within the drug class, continue to #10.

   If no, do not approve.
   DENIAL TEXT: Use reason code G09
   Our guideline named **Cook County GENERAL FORMULARY EXCEPTION GUIDELINE** requires that you have tried and failed at least **TWO** (2) of our preferred drugs that are in the same drug class, if alternatives are available. Please discuss with your doctor, if other medications on the formulary would be appropriate to treat your condition. If appropriate your provider may submit clinical documentation to support utilization of a non-formulary medication. Formulary alternatives include but are not limited to <free text formulary alternatives>.

   FREE TEXT: Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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Cook County GENERAL FORMULARY EXCEPTION GUIDELINE

INITIAL REQUESTS (CONTINUED)

10. Has the patient tried and failed two clinically appropriate formulary alternatives, which are indicated for the specified diagnosis, or have compendia data or guideline data to support their use (or one formulary alternative if two are not available)?
    Example: Lactulose is a formulary alternative for Xifaxan in the treatment of Hepatic Encephalopathy.
    Note: If MI guideline is available, reviewer can consult to identify potential alternatives; but formulary status of those alternatives needs to be verified.

    If yes, **approve according to the limitations within the MI guideline or up to 12 months by HICL based on formulary quantity limits if guideline not available.**

    If there are no preferred alternatives for the specified diagnosis, continue to #11.

    If no, do not approve.
    DENIAL TEXT: Use reason code G09.
    Our guideline named **Cook County GENERAL FORMULARY EXCEPTION GUIDELINE** requires that you have tried and failed at least **TWO** (2) of our preferred drugs that are in the same drug class, if alternatives are available. If there are no preferred drugs in the same drug class, you must try and fail two preferred alternatives in the same therapeutic class or satisfy clinical criteria for your diagnosis. Please discuss with your doctor, if other medications on the formulary would be appropriate to treat your condition. If appropriate your provider may submit clinical documentation to support utilization of a non-formulary medication. Formulary alternatives include but are not limited to: <free text formulary alternatives>.

    FREE TEXT: Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or provide us with more information if it will allow us to approve this request.

11. Is there a standard Medicaid/Commercial/NSA guideline available for the requested drug?
    Example: Oncology drugs, Jynarque

    If yes, **review according to the guideline. Cite approval or denial based on guideline criteria.**
    If no, continue to #12.

    Note 1: If the approval text includes a QL, check if requested dosage aligns with QL of approval text.
    Note 2: Approval duration should match approval duration listed on the guideline approval text.

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Cook County GENERAL FORMULARY EXCEPTION GUIDELINE

INITIAL REQUESTS (CONTINUED)

12. Is there compendia support for the requested indication?

    If yes, **approve up to 12 months by HICL based on formulary quantity limits according to FDA approved dosing.**
    If no, do not approve.
    DENIAL TEXT: Use reason code G09.

RENEWAL REQUESTS

1. Is there a Standard MI Guideline available?

    If yes, **review according to the guideline. Cite approval or denial based on guideline criteria.**
    If no, continue to #2.

2. Has the patient previously been through the FE process, is established on the non-formulary (NF) drug, and has documented positive clinical response to the therapy?

    If yes, **approve up to 12 months by HICL based on formulary quantity limits.**
    If no, do not approve.

    Note: If the patient has never gone through the FE process via CountyCare, initiate the first time **FE INITIAL REQUEST**.

    DENIAL TEXT: In order for your request to be approved, your provider needs to tell us that you have tried and failed at least **TWO** (2) of our preferred drugs that are in the same drug class if alternatives are available. If there are no preferred drugs in the same drug class, you must try and fail two preferred alternatives in the same therapeutic class or satisfy clinical criteria for your diagnosis.

RATIONALE

Provide guidance for review of formulary exception requests.

Created: 12/20
Effective: 07/15/22 Client Approval: 07/07/21 P&T Approval: N/A

COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

COMPOUNDED MEDICATIONS

Note: This guideline is provided for requests for compounded medications that exceed the max claim paid amount of $250. Chart notes or other appropriate documentation from the prescriber will be required to verify need for therapy.

GUIDELINES FOR USE

1. Is the medication requested using bulk chemicals **not** in a compound?

   If yes, do not approve.
   DENIAL TEXT: Approval requires the use of bulk chemicals in a compounded medication.
   If no, continue to #2.

2. Is the request for an IV antibiotic, antifungal, anti-infective, or total parenteral nutrition (TPN)?

   If yes, **approve by duration WITHOUT a limit of fills for up to 12 months.**
   If no, continue to #3.

3. Has the patient tried all commercially available products to treat the condition for which the compounded medication is prescribed?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: Approval requires a trial of all commercially available products used to treat the condition for which the compounded medication is prescribed and documentation of evidence to support the use of the compounded medication to treat the patient's disease state.

4. Has the prescriber submitted evidence (e.g. Clinical Pharmacology, Micromedex, or article from an authoritative peer-reviewed medical and scientific literature journal) supporting the use of the compounded medication to treat the patient's disease state?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Approval requires a trial of all commercially available product used to treat the condition for which the compounded medication is prescribed and documentation of evidence (e.g. Clinical Pharmacology, Micromedex, or article from an authoritative peer-reviewed medical and scientific literature journal) to support the use of the compounded medication to treat the patient's disease state.

5. **Approve for up to 12 months.**

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COMPOUNDED MEDICATIONS

RATIONALE

Client will cover the cost of compound medications that exceed a max paid claim amount of $250 if the patient has tried and failed at least one commercially available product to treat the condition for which the compounded medication is prescribed. If more than one commercially available alternative is available, then a trial of additional commercially available medications will be required. Medical evidence must support the use of the compounded medication to treat the patient's disease state.

Created: 04/19
Effective: 09/18/20 Client Approval: 09/01/20 P&T Approval: N/A

COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

ERYTHROPOIESIS STIMULATING AGENTS

Generic	Brand	HICL	GCN	Exception/Other
DARBEPOETIN	ARANESP	22890		
EPOETIN ALFA	EPOGEN, PROCRIT	04553		
EPOETIN ALFA-EPBX	RETACRIT	44931		
METHOXY PEG-EPOETIN BETA	MIRCERA	35005		

GUIDELINES FOR USE

Note: Please use the criteria for the specific drug requested.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

PROCRIT

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) **AND** meet the following criterion?
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve Procrit for 12 months by HICL with a quantity limit of #12mL per 28 days. APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 11g/dL
   - The patient's hemoglobin level has decreased at least 2g/dL below their baseline level

   If yes, **approve Procrit for 12 months by HICL with a quantity limit of #12mL per 28 days. APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy **AND** meet the following criterion?
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve Procrit for 12 months by HICL with a quantity limit of #12mL per 28 days APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #4.

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INITIAL CRITERIA - PROCRIT (CONTINUED)

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has had a trial or contraindication to ribavirin dose reduction

   If yes, **approve Procrit for 6 months by HICL with a quantity limit of #12mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #5.

5. Is the patient undergoing elective, noncardiac, or nonvascular surgery **AND** meet the following criterion?
   - The patient has a hemoglobin level of less than 13g/dL

   If yes, **approve requested strength of Procrit for 1 month as follows:**
   - **2,000U/mL by GPID for #12mL per 28 days.**
   - **3,000U/mL by GPID for #12mL per 28 days.**
   - **4,000U/mL by GPID for #12mL per 28 days.**
   - **10,000U/mL by GPID for #12mL per 28 days.**
   - **20,000U/mL by GPID for #12mL per 28 days.**
   - **40,000U/mL by GPID for #6mL per 28 days.**
   - **20,000U/2mL by NDC for #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the Procrit initial guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA - PROCRIT (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Procrit)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires ONE of the following:**
   1. You have a hemoglobin level of less than 11g/dL
   2. Your hemoglobin level has decreased at least 2g/dL below their baseline level

D. **If you have anemia related to zidovudine therapy, approval also requires:**
   1. You have a hemoglobin level of less than 10g/dL

E. **If you have anemia due to concurrent hepatitis C treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried a lower ribavirin dosage, unless there is medical reason why you cannot (contraindication)
   2. You have a hemoglobin level of less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have a hemoglobin level of less than 13g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA (CONTINUED)

ARANESP

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has a history of trial and failure, contraindication or intolerance to Epogen or Procrit

   If yes, **approve Aranesp for 12 months by HICL with quantity limit of #4mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet the following criteria?
   - The patient has a hemoglobin level of less than 11g/dL **OR**
   - The patient's hemoglobin level has decreased at least 2g/dL below their baseline level
   - The patient has a history of trial and failure, contraindication or intolerance to Epogen or Procrit

   If yes, **approve Aranesp for 12 months by HICL with a quantity limit of #4mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has had a trial or contraindication to ribavirin dose reduction
   - The patient has a history of trial and failure, contraindication or intolerance to Epogen or Procrit

   If yes, **approve Aranesp for 6 months by HICL with a quantity limit of #4mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the Aranesp initial guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA - ARANESP (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Aranesp)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
   2. You have tried Epogen or Procrit

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires you have tried Epogen or Procrit and ONE of the following:**
   1. You have a hemoglobin level of less than 11g/dL
   2. Your hemoglobin level has decreased at least 2g/dL below their baseline level

D. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried a lower ribavirin dosage, unless there is medical reason why you cannot (contraindication)
   2. You have a hemoglobin level of less than 10g/dL
   3. You have tried Epogen or Procrit

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA (CONTINUED)

EPOGEN

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet the following criterion?
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve Epogen for 12 months by HICL with a quantity limit of #12mL per 28 days**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 11g/dL
   - The patient's hemoglobin level has decreased at least 2g/dL below their baseline level

   If yes, **approve Epogen for 12 months by HICL with a quantity limit of #12mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criterion?
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve Epogen for 12 months by HICL with a quantity limit of #12mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has had a trial or contraindication to ribavirin dose reduction

   If yes, **approve Epogen for 6 months by HICL with a quantity limit of #12mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #5.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA - EPOGEN (CONTINUED)

5. Is the patient undergoing elective, noncardiac, or nonvascular surgery and meet the following criterion?
   - The patient has a hemoglobin level of less than 13g/dL

   If yes, **approve the requested strength of Epogen for 1 month as follows:**
   - **2,000U/mL: by GPID for #12mL per 28 days.**
   - **3,000U/mL: by GPID for #12mL per 28 days.**
   - **4,000U/mL: by GPID for #12mL per 28 days.**
   - **10,000U/mL: by GPID for #12mL per 28 days.**
   - **20,000U/mL: by GPID for #12mL per 28 days.**
   - **20,000U/2mL: by NDC with no quantity limit.**

   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (EPOGEN)** requires the following rule(s) be met for approval:

   A. You have ONE of the following diagnoses:
      1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
      2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
      3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
      4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
      5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery

   B. **If you have anemia associated with chronic kidney disease, approval also requires:**
      1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL

   C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires ONE of the following:**
      1. You have a hemoglobin level of less than 11g/dL
      2. Your hemoglobin level has decreased at least 2g/dL below their baseline level

   D. **If you have anemia related to zidovudine, approval also requires:**
      1. You have a hemoglobin level of less than 10g/Dl

   (Initial Epogen denial text continued on next page)

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA - EPOGEN (CONTINUED)

E. **If you have anemia due to concurrent hepatitis C treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried a lower ribavirin dosage, unless there is medical reason why you cannot (contraindication)
   2. Your hemoglobin level is less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have a hemoglobin level of less than 13g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RETACRIT

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has a history of trial and failure, contraindication or intolerance to Epogen or Procrit

   If yes, **approve Retacrit for 12 months by HICL with a quantity limit of #12mL per 28 days. APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet the following criteria?
   - The patient has a hemoglobin level of less than 11g/dL **OR** the patient's hemoglobin level has decreased at least 2g/dL below their baseline level
   - The patient has a history of trial and failure, contraindication or intolerance to Epogen or Procrit

   If yes, **approve Retacrit for 12 months by HICL with a quantity limit of #12mL per 28 days. APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has a history of trial and failure, contraindication or intolerance to Epogen or Procrit

   If yes, **approve Retacrit for 12 months by HICL with a quantity limit of #12mL per 28 days. APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #4.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA - RETACRIT (CONTINUED)

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has had a trial or contraindication to ribavirin dose reduction
   - The patient has a history of trial and failure, contraindication or intolerance to Epogen or Procrit

   If yes, **approve Retacrit for 6 months by HICL with a quantity limit of #12mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #5.

5. Is the patient undergoing elective, noncardiac, or nonvascular surgery and meet the following criteria?
   - The patient has a hemoglobin level of less than 13g/dL
   - The patient has a history of trial and failure, contraindication or intolerance to Epogen or Procrit

   If yes, **approve the requested strength of Retacrit for 1 month by GPID with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10000U/mL: #12mL in 28 days.**
   - **20000U/mL: #12mL in 28 days.**
   - **40000U/mL: #6mL in 28 days.**
   - **20000U/2mL: #12mL in 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the Retacrit initial guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA - RETACRIT (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (RETACRIT)** requires that the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery

B. **If you have anemia associated with chronic kidney disease (CKD), approval also requires:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
   2. You have tried Epogen or Procrit.

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires you have tried Epogen or Procrit and ONE of the following:**
   1. You have a hemoglobin level of less than 11g/dL
   2. Your hemoglobin has decreased at least 2g/dL below their baseline level

D. **If you have anemia related to zidovudine therapy, approval also requires:**
   1. You have a hemoglobin level of less than 10g/dL
   2. You have tried Epogen or Procrit

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried a ribavirin dose reduction, unless there is a medical reason why you cannot
   2. You have a hemoglobin level of less than 10g/dL
   3. You have tried Epogen or Procrit

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have a hemoglobin level of less than 13g/dL
   2. You have tried Epogen or Procrit

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA (CONTINUED)

MIRCERA

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Mircera initial guideline.

2. Is the patient 18 years of age or older **AND** meet the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has a history of trial and failure, contraindication or intolerance to Epogen or Procrit

   If yes, **approve Mircera for 12 months by HICL with a quantity limit of #0.6mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

3. Is the patient between 5 and 17 years of age **AND** meet the following criteria:
   - The patient is on hemodialysis
   - The patient is converting from another erythropoiesis-stimulating agent (ESA) (i.e., epoetin alfa, darbepoetin alfa) after the hemoglobin level has been stabilized with the ESA

   If yes, **approve Mircera for 12 months by HICL with a quantity limit of #0.6mL per 28 days.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (MIRCERA)** requires the following rule(s) be met for approval:
   A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   B. **If you are 18 years of age or older, approval also requires:**
      1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
      2. You have tried Epogen or Procrit
   C. **If you are between 5 and 17 years of age, approval also requires:**
      1. You are on hemodialysis
      2. You are changing from another erythropoiesis-stimulating agent (ESA) (i.e., epoetin alfa, darbepoetin alfa) after the hemoglobin level has been stabilized with the erythropoiesis stimulating agent

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

PROCRIT

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL if not on dialysis
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis
   - The patient has a hemoglobin level that has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required
   - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required

   If yes, **approve Procrit for 12 months by HICL with a quantity limit of #12mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet the following criterion?
   - The patient has a hemoglobin level between 10 g/dL and 12g/dL

   If yes, **approve Procrit for 12 months by HICL with a quantity limit of #12mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve Procrit for 12 months by HICL with a quantity limit of #12mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve Procrit for 6 months by HICL with a quantity limit of #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Procrit renewal guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA - PROCRIT (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (PROCRIT)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to with chronic kidney disease
   2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are not on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. You have a hemoglobin level has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

D. **If you have anemia related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA (CONTINUED)

ARANESP

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL if not on dialysis
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis
   - The patient has a hemoglobin level that has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required
   - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required

   If yes, **approve Aranesp for 12 months by HICL with a quantity limit of #4mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet the following criterion?
   - The patient has a hemoglobin level between 10 g/dL and 12g/dL

   If yes, **approve Aranesp for 12 months by HICL with a quantity limit of #4mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet the following criterion?
   - The patient has a hemoglobin level between 10 g/dL and 12g/dL

   If yes, **approve Aranesp for 6 months by HICL with a quantity limit of #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Aranesp renewal guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA - ARANESP (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (ARANESP)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease (CKD), renewal requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are not on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin has reached 10g/dL (if you are not on dialysis) or 11g/dL (if you are on dialysis) and dose reduction/interruption is required

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

D. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA (CONTINUED)

EPOGEN

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL if not on dialysis
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis
   - The patient has a hemoglobin level that has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required
   - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required

   If yes, **approve Epogen for 12 months by HICL with a quantity limit of #12mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet the following criterion?
   - The patient has a hemoglobin level between 10 g/dL and 12g/dL

   If yes, **approve Epogen for 12 months by HICL with a quantity limit of #12mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criterion?
   - The patient has a hemoglobin level between 10 g/dL and 12g/dL

   If yes, **approve Epogen for 12 months by HICL with a quantity limit of #12mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet the following criterion?
   - The patient has a hemoglobin level between 10 g/dL and 12g/dL

   If yes, **approve Epogen for 6 months by HICL with a quantity limit of #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Epogen renewal guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA - EPOGEN (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (EPOGEN)** requires following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are not on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

D. **If you have anemia related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA (CONTINUED)

RETACRIT

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL if not on dialysis
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis
   - The patient has a hemoglobin level that has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required
   - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required

   If yes, **approve Retacrit for 12 months by HICL with a quantity limit of #12mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet the following criterion?
   - The patient has a hemoglobin level between 10 g/dL and 12g/dL

   If yes, **approve Retacrit for 12 months by HICLwith a quantity limit of #12mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criterion?
   - The patient has a hemoglobin level between 10 g/dL and 12g/dL

   If yes, **approve Retacrit for 12 months by HICLwith a quantity limit of #12mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet the following criterion?
   - The patient has a hemoglobin level between 10 g/dL and 12g/dL

   If yes, **approve Retacrit for 6 months by HICLwith a quantity limit of #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Retacrit renewal guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA - RETACRIT (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (RETACRIT)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are not on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

D. **If you have anemia related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You to have a hemoglobin level (amount of oxygen-containing protein) between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA (CONTINUED)

MIRCERA

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD)?

   If yes, continue to #2.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Mircera renewal guideline.

2. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   - **If the patient is currently receiving dialysis treatment:**
     - The patient has a hemoglobin level of less than 11g/dL **OR**
     - The patient has a hemoglobin level that has reached 11g/dL and dose reduction/interruption is required
   - **If the patient is NOT receiving dialysis treatment:**
     - The patient has a hemoglobin level of less than 10g/dL **OR**
     - The patient has a hemoglobin level that has reached 10g/dL and dose reduction/interruption is required

   If yes, **approve Mircera for 12 months by HICL with a quantity limit of #0.6mL per 28 days.**

   If no, continue to #3.

3. Is the patient between 5 and 17 years of age and meet all of the following criteria?
   - The patient is currently receiving dialysis treatment
   - The patient has **ONE** of the following:
     - A hemoglobin level of less than 11g/dL
     - A hemoglobin level that has reached 11g/dL and dose reduction/interruption is required

   If yes, **approve Mircera for 12 months by HICL with a quantity limit of #0.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Mircera renewal guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA - MIRCERA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (MIRCERA)** requires the following rule(s) be met for renewal:

A. **If you are 18 years of age or older and are receiving dialysis treatment, renewal also requires ONE of the following:**
   a. You have a hemoglobin level (amount of oxygen-containing protein) of less than 11g/dL
   b. You have a hemoglobin level (amount of oxygen-containing protein) that has reached 11g/dL and dose reduction/interruption is required

B. **If you are 18 years of age or older and NOT receiving dialysis treatment, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
   2. You have a hemoglobin level (amount of oxygen-containing protein) that has reached 10g/dL and dose reduction/interruption is required

C. **If you are between 5 and 17 years of age, renewal also requires:**
   1. You are currently receiving dialysis treatment
   2. You have ONE of the following:
      a. A hemoglobin level (amount of oxygen-containing protein) of less than 11g/dL
      b. A hemoglobin level (amount of oxygen-containing protein) that has reached 11g/dL and dose reduction/interruption is required

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Procrit, Epogen, Mircera, Retacrit and Aranesp.

REFERENCES

- Retacrit [Prescribing Information]. Lake Forest, IL: Pfizer Inc. May 2020.
- Procrit [Prescribing Information]. Thousand Oaks, CA: Amgen, September 2017.
- Epogen [Prescribing Information]. Thousand Oaks, CA: Amgen, September 2017.
- Aranesp [Prescribing Information]. Thousand Oaks, CA: Amgen, September 2017.
- Mircera [Prescribing Information]. St. Gallen, Switzerland: Vifor, June 2018.

Created: 04/20
Effective: 02/01/21 Client Approval: 12/29/20 P&T Approval: N/A

COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

GENERAL AGE LIMITATIONS (ILLINOIS MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other

GUIDELINES FOR USE

1. Is the request for an age restriction override?

   If yes, continue to #2.
   If no, this guideline does not apply.

2. Does the requested drug for the patient's age meet **ALL** of the following criteria?
   - The patient does not have any age contraindications
   - The patient's age for the requested drug meets **ONE** of the following:
     - A Food and Drug Administration (FDA)-approved indication OR
     - A medically accepted indication and it is considered safe and effective by approved compendia (medical references), peer-reviewed medical literature, or accepted standards of medical practice.

   If yes, **approve for 12 months by HICL.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **GENERAL AGE LIMITATIONS** requires:
   - The patient does not have any age contraindications AND
   - The patient's age for the requested drug meets **ONE** of the following:
     - A Food and Drug Administration (FDA)-approved indication OR
     - A medically accepted indication and it is considered safe and effective by approved compendia (medical references), peer-reviewed medical literature, or accepted standards of medical practice.

RATIONALE

To ensure appropriate use of drugs consistent with FDA-approved indications and Illinois Medicaid age limitation requirements.

REFERENCES

Cook County Healthcare and Hospital Systems Plan. Formulary Prior Authorization Criteria. [Accessed: February 28, 2020].

Created: 03/20
Effective: 07/17/20 Client Approval: 07/02/20 P&T Approval: N/A

COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

GENERAL CRITERIA FOR PRIOR APPROVAL OF DIRECT-ACTING ANTIVIRALS (DAA)
(ILLINOIS MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
SOFOSBUVIR/VELPATASVIR/ VOXILAPREVIR	VOSEVI	44428		
LEDIPASVIR/SOFOSBUVIR	HARVONI	41457		
SOFOSBUVIR/VELPATASVIR	EPCLUSA	43561		
SOFOSBUVIR	SOVALDI	40795		
DACLATASVIR DIHYDROCHLORIDE	DAKLINZA	41377		
OMBITASVIR/PARITAPREVIR/ RITONAVIR/DASABUVIR	VIEKIRA XR, VIEKIRA PAK	41644		
ELBASVIR/GRAZOPREVIR	ZEPATIER	43030		
GLECAPREVIR/PIBRENTASVIR	MAVYRET	44453		
OMBITASVIR/PARITAPREVIR/ RITONAVIR	TECHNIVIE	41734		

DO NOT OVERRIDE OR APPROVE WITHOUT SUBMITTING FOR PHARMACIST REVIEW.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Chronic Hepatitis C infection and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has genotype 1, 2, 3, 4, 5 or 6 as confirmed by lab documentation and quantitative baseline HCV-RNA
   - The patient has a documented Metavir/fibrosis score that is determined on either Liver Biopsy, Transient Elastography (FibroScan), FibroTest/FibroSure, or FibroMeter
   - The requested drug regimen is prescribed by **ONE** of the following:
     - A gastroenterologist, hepatologist, transplant hepatologist, or infectious disease specialist, **OR**
     - The prescriber can be any practitioner licensed to prescribe, or licensed to prescribe in collaboration with a physician who holds a current unrestricted license to practice medicine. In addition, if the prescriber is not one of the above mentioned specialists, the prescriber must engage in a one-time consultation with one of these specialists within the 3 months prior to the request for prior authorization. This one-time consultation may be via telephone, video-conference, or tele-health technology. The records containing a specialist recommendation for treatment with a DAA regimen must be submitted with the request for prior approval **AND** the prescriber must provide clinic or consultation notes from specialist consultation.

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GENERAL CRITERIA FOR PRIOR APPROVAL OF DIRECT-ACTING ANTIVIRALS (DAA) (ILLINOIS MEDICAID)

GUIDELINES FOR USE (CONTINUED)

2. Does the patient have **ALL** of the following lab tests completed (within the past 3 months for cirrhotic patients or within the past 6 months for non-cirrhotic patients) prior to the requested approval, unless otherwise noted?
   - Baseline quantitative HCV RNA level (within 1 year of request for prior approval)
   - Liver function tests including: alanine aminotransferase (ALT), aminotransferase (AST)
   - Complete blood count (CBC)
   - Kidney function test: glomerular filtration rate (GFR)
   - International Normalised Ratio (INR), albumin, and bilirubin, for stage 4 fibrosis only
   - Negative HBV screen; or if positive, quantitative HBV DNA and verification of treatment regimen (any time prior to initiation of therapy)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - In the opinion of the prescriber, the patient is able to make appropriate decisions about treatment and comply with dosing and other instructions, and is capable of completing therapy as prescribed (the following must be submitted):
     - The prescriber must provide a copy of a signed patient commitment letter for all hepatitis C treatment regiments

     [Note: Non-adherence with current regimen (>7days) or patient's failure to obtain refills in a timely manner may result in discontinuation of current prior approval. Non-adherence or failure to obtain refills that result from situations that are beyond the patient's control will not result in discontinuation of a prior approval]
   - The requested treatment regimen is not for an indication outside of the FDA-approved labeling
   - The patient has no existing contraindications or significant drug interactions to treatment as specified in the product labeling
   - The prescribing provider is responsible for addressing ongoing misuse of alcohol and/or continued use of illicit IV drugs (if appropriate, and physician attestation is acceptable)
   - The patient has no history of an incomplete course of treatment with direct-acting antivirals (DAAs), with the following caveat:
     - Prior treatment with telaprevir, boceprevir, and DAA regimens used in combination with interferons is NOT taken into consideration for purposes of this criterion

(Guideline question continued on next page)

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GENERAL CRITERIA FOR PRIOR APPROVAL OF DIRECT-ACTING ANTIVIRALS (DAA) (ILLINOIS MEDICAID)

GUIDELINES FOR USE (CONTINUED)

- The prescriber agrees to submit HCV RNA levels for patients prescribed DAAs within 8 weeks after beginning treatment, 12 weeks post treatment, and 24 weeks post treatment.
  [Note: If at any point the patient's viral load is undetectable, the prescriber is not required to submit any subsequent test. Prescriber's failure to submit a lab report in a timely fashion due to patient's non-cooperation may result in denial of re-treatment, should that situation arise. However, situations beyond the control of the prescriber or the patient will not result in a denial of re-treatment under this criterion]

  If yes, continue to #4.
  If no, do not approve.
  DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the request for a Hepatitis C medication that is listed as "Preferred with PA" on the current IL State PDL? https://www.illinois.gov/hfs/MedicalProviders/Pharmacy/preferred/Pages/default.aspx

   If yes, **approve for 3 months by HICL.**
   If no, continue to #5.

5. Has the prescriber provided medical justification (contraindication, serious drug interaction, etc.) why the patient cannot use a preferred IL PDL Hepatitis C medication?

   If yes, **approve for 3 months by HICL.**
   If no, do not approve.
   DENIAL TEXT: Use reason code G09 and any applicable denial text at the end of the guideline.

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GENERAL CRITERIA FOR PRIOR APPROVAL OF DIRECT-ACTING ANTIVIRALS (DAA) (ILLINOIS MEDICAID)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **GENERAL CRITERIA FOR PRIOR APPROVAL OF DIRECT-ACTING ANTIVIRALS (DAA)** requires a FDA-approved indication. In addition, the following must be met:

- The drug is preferred on the IL State PDL **OR** if the drug is non-preferred, the patient has a documented valid medical reason that the preferred medications cannot be tried (contraindication, serious drug interaction)
- The patient is 12 years of age or older
- The patient has genotype 1, 2, 3, 4, 5 or 6 as confirmed by lab documentation and quantitative baseline HCV-RNA
- The patient has a documented Metavir/fibrosis score that is determined on either Liver Biopsy, Transient Elastography (FibroScan), FibroTest/FibroSure, or FibroMeter
- The requested drug regimen is prescribed by ONE of the following:
  - A gastroenterologist, hepatologist, transplant hepatologist, or infectious disease specialist, **OR**
  - The prescriber can be any practitioner licensed to prescribe, or licensed to prescribe in collaboration with a physician who holds a current unrestricted license to practice medicine. In addition, if the prescriber is not one of the above mentioned specialists, the prescriber must engage in a one-time consultation with one of these specialists within the 3 months prior to the request for prior authorization. This one-time consultation may be via telephone, video-conference, or tele-health technology. The records containing a specialist recommendation for treatment with a DAA regimen must be submitted with the request for prior approval **AND** the prescriber must provide clinic or consultation notes from specialist consultation
- The patient has the following lab tests completed within the past 3 months for cirrhotic patients or within the past 6 months for non-cirrhotic patients prior to the requested approval, unless otherwise noted:
  - Baseline quantitative HCV RNA level (within 1 year of request for prior approval)
  - Liver function tests including: alanine aminotransferase (ALT), aminotransferase (AST)
  - Complete blood count (CBC)
  - Kidney function test: glomerular filtration rate (GFR)
  - International Normalised Ratio (INR), albumin, and bilirubin, for stage 4 fibrosis only
  - Negative HBV screen; or if positive, quantitative HBV DNA and verification of treatment regimen (anytime prior to initiation of therapy)
- In the opinion of the prescriber, the patient is able to make appropriate decisions about treatment and comply with dosing and other instructions, and is capable of completing therapy as prescribed (the following must be submitted):
  - The prescriber must provide a copy of a signed patient commitment letter for all hepatitis C treatment regiments

(Denial text continued on next page)

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GENERAL CRITERIA FOR PRIOR APPROVAL OF DIRECT-ACTING ANTIVIRALS (DAA) (ILLINOIS MEDICAID)

GUIDELINES FOR USE (CONTINUED)

- The requested treatment regimen is not for an indication outside of the FDA-approved labeling
- The patient has no existing contraindications or significant drug interactions to treatment as specified in the product labeling
- The prescribing provider is responsible for addressing ongoing misuse of alcohol and/or continued use of illicit IV drugs (if appropriate)
- The patient has no history of an incomplete course of treatment with direct-acting antivirals (DAAs), with the following caveat:
  - Prior treatment with telaprevir, boceprevir, and DAA regimens used in combination with interferons is NOT taken into consideration for purposes of this criterion
- The prescriber agrees to submit HCV RNA levels for patients prescribed DAAs within 8 weeks after beginning treatment, 12 weeks post treatment, and 24 weeks post treatment.
  [**Note:** If at any point the patient's viral load is undetectable, the prescriber is not required to submit any subsequent test. Prescriber's failure to submit a lab report in a timely fashion due to patient's non-cooperation may result in denial of re-treatment, should that situation arise. However, situations beyond the control of the prescriber or the patient will not result in a denial of re-treatment under this criterion]

The medications will NOT be approved for the following:

- Non-adherence with current regimen (>7days) or patient's failure to obtain refills in a timely manner may result in discontinuation of current prior approval. Non-adherence or failure to obtain refills that result from situations that are beyond the patient's control will not result in discontinuation of a prior approval
- For required submission of HCV RNA levels: Prescriber's failure to submit a lab report in a timely fashion due to patient's non-cooperation may result in denial of re-treatment, should that situation arise. However, situations beyond the control of the prescriber or the patient will not result in a denial of re-treatment under this criterion

RATIONALE

To ensure appropriate use of Direct-Acting Antiviral (DAA) agents are consistent with FDA-approved indications and Illinois Medicaid requirements.

REFERENCES

- Cook County Healthcare and Hospital Systems Plan. Formulary Prior Authorization Criteria. [Accessed: February 05, 2019].
- Illinois Department of Healthcare and Family Services. Criteria for Prior Approval of Direct-Acting Antivirals (DAAs) for Hepatitis C. Available: https://www.illinois.gov/hfs/SiteCollectionDocuments/HFSHepCDAACriteriaWordFINAL11012018.pdf [Accessed: February 21st, 2019].

Created: 03/19
Effective: 11/08/21 Client Approval: 09/27/21 P&T Approval: 06/21

COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

GENERAL QUANTITY LIMIT CRITERIA (ILLINOIS MEDICAID)

Note: Please use this guideline only for the review of quantity limit overrides.

This drug requires a request for prior authorization.

GUIDELINES FOR USE

1. Is the request for a quantity limit (QL) override?

   If yes, continue to #2.
   If no, this guideline does not apply.

2. Is the request a QL override for a CMS protected class medication?

   If yes, **approve the requested Quantity per Day Supply for 12 months by GPID**
   If no, continue to #3.

3. Is the quantity requested within the dosing for an FDA approved indication OR is the quantity requested supported by peer-reviewed medical literature OR standard of care guidelines (GOLD, IDSA, AASLD, etc.)?

   If yes, **approve the requested Quantity per Day Supply for 12 months by GPID.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **GENERAL QUANTITY LIMIT CRITERIA** requires the requested quantity per day supply be supported per FDA-approved indication, peer-reviewed medical literature, or standard of care guidelines.

   Optional Indication DENIAL TEXT: Your provider requested this drug for the treatment of <diagnosis>, but it is not clinically supported for this use. It is indicated for the treatment of <insert text>. Your provider did not advise that this drug is being used for any of these approved medical reasons. Please talk with your provider about other treatment options.]

RATIONALE

To ensure appropriate use of drugs consistent with FDA-approved indications and peer-reviewed literature.

REFERENCES

Created: 04/20
Effective: 07/03/20 Client Approval: 06/17/20

COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

ITRACONAZOLE-SPORANOX

Generic	Brand	HICL	GCN	Exception/Other
ITRACONAZOLE	SPORANOX		49101 49100	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of *tinea corporis*, *tinea cruris*, or *tinea pedis*?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of onychomycosis (tinea unguium) **AND** meet the following criterion?
   - There is documentation of a positive dermatophyte culture as indicated by a copy of the lab report

   If yes, continue to #3.
   If no, continue to #9.

3. Is the onychomycosis involving the toenails **AND** the patient meets the following criterion?
   - The patient has **NOT** been treated for toenail onychomycosis in the last 12 months (per MRF or prior authorization history)

   If yes, continue to #4.
   If no, continue to #6.

4. Is the request for Sporanox capsules?

   If yes, **approve Sporanox capsules (GPID 49101) for 12 weeks with a quantity limit of #2 capsules per day.**
   If no, continue to #5.

5. Is the request for Sporanox solution **AND** the patient is unable to swallow capsules?

   If yes, **approve Sporanox solution (GPID 49100) for 12 weeks with a quantity limit of #20mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline**.**

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ITRACONAZOLE-SPORANOX

GUIDELINES FOR USE (CONTINUED)

6. Is the request for onychomycosis involving the fingernails **AND** the patient meets the following criterion?
   - The patient has **NOT** been treated for fingernail onychomycosis in the last 6 months (per MRF or prior authorization history)

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline**.**

7. Is the request for Sporanox capsules?

   If yes, **approve Sporanox capsules (GPID 49101) up to #28 capsules per month for 2 months (56 x 100mg capsules for 5 weeks: #2 of 100mg capsules BID for one week, stop 3 weeks & repeat).**
   If no, continue to #8.

8. Is the request for Sporanox solution **AND** the patient is unable to swallow capsules?

   If yes, **approve Sporanox solution (GPID 49100) with a quantity limit of #560mL for 5 weeks.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline**.**

9. Does the patient have a diagnosis of esophageal candidiasis **AND** meet the following criterion?
   - The patient has had a trial of or contraindication to fluconazole

   If yes, **approve Sporanox solution (GPID 49100) for course of treatment up to 20mL per day for up to 3 weeks.**
   If no, continue to #10.

10. Does the patient have a diagnosis of a systemic fungal infection such as blastomycosis, histoplasmosis, or aspergillosis?

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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ITRACONAZOLE-SPORANOX

GUIDELINES FOR USE (CONTINUED)

11. Is the request for Sporanox capsules?

    If yes, **approve Sporanox capsules (GPID 49101) for course of treatment (200mg to 400mg daily for minimum of 3 months).**
    If no, continue to #12.

12. Is the request for Sporanox solution **AND** the patient is unable to swallow capsules?

    If yes, **approve Sporanox solution (GPID 49100) with a quantity limit of #40mL per day per course of treatment.**
    If no, do not approve.
    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **ITRACONAZOLE (Sporanox)** requires the following rule(s) be met for approval:

    A. You have a diagnosis of onychomycosis of the toenails or fingernails (toenail or fingernail fungus), esophageal candidiasis (throat fungus), or a systemic fungal infection such as blastomycosis, histoplasmosis, or aspergillosis (type of fungal infection in or outside of the lungs)
    B. **If you have onychomycosis of the toenails, approval requires:**
    1. There is documentation of a positive dermatophyte (type of fungi) culture as indicated by a copy of the lab report
    2. You have **NOT** been treated for toenail onychomycosis in the last 12 months (per Medication Request Form or prior authorization history)
    3. Requests for the Sporanox solution requires that you are unable to swallow capsules
    C. **If you have onychomycosis of the fingernails, approval requires:**
        1. There is documentation of a positive dermatophyte (type of fungi) culture as indicated by a copy of the lab report
        2. You have **NOT** been treated for fingernail onychomycosis in the last 6 months (per Medication Request Form or prior authorization history)
        3. Requests for the Sporanox solution requires that you are unable to swallow capsules
    D. **If you have esophageal candidiasis, approval requires you** had a trial of fluconazole, unless there is a medical reason why you cannot (contraindication)
    E. **If you have a diagnosis of a systemic fungal infection such as blastomycosis, histoplasmosis, or aspergillosis:**
        1. Requests for the Sporanox solution requires that you are unable to swallow capsules

    Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ITRACONAZOLE-SPORANOX

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sporanox.

REFERENCES

- Sporanox capsules [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. May 2018.
- Sporanox solution [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. October 2017.

Created: 06/20
Effective: 07/03/20 Client Approval: 06/17/20 P&T Approval: N/A

LABELED AND COMPENDIA SUPPORTED INDICATIONS GUIDELINE

Generic	Brand	HICL	GCN	Exception/Other
ANTIHEMOPHIL.FVIII,FULL LENGTH	ADVATE		32723, 27008	
ANTIHEMO.FVIII,FULL LENGTH PEG	ADYNOVATE		40207, 40208, 40209, 40213, 43009, 43013, 43353	
ANTIHEM.FVIII,SIN-CHN,B-DM TRU	AFSTYLA		41497, 41499, 41501, 41502, 41503, 43089, 43093	
ANTIHEMOPHILIC FACTOR/VWF	ALPHANATE		27332, 27333, 27334, 27335, 37015	
FACTOR IX	ALPHANINE SD		91671, 21647	
FACTOR IX REC, FC FUSION PROTN	ALPROLIX		36333, 36334, 36335, 36336, 40816, 42556	
FACTOR IX HUMAN RECOMBINANT	BENEFIX		25154, 25153, 25152, 98600, 31007	
COAGULATION FACTOR X	COAGADEX		39952, 39954	
FACTOR XIII	CORIFACT		29584	
PIMECROLIMUS	ELIDEL		15348	
APIXABAN	ELIQUIS		30239, 33935, 44357	
ANTIHEMOPH.FVIII REC,FC FUSION	ELOCTATE		43116, 36666, 43115, 43114, 36657, 36658, 36662,	

			36663, 36664, 36665	
MORPHINE SULFATE/NALTREXONE	EMBEDA		37687, 37688, 37689, 37692, 37685, 37686	
CRISABOROLE	EUCRISA		42792	
ANTI-INHIBITOR COAGULANT COMP.	FEIBA NF		25220, 26335, 23816	
PROPRANOLOL HCL	HEMANGEOL		36526	
ANTIHEMOPHILIC FACTOR, HUMAN	HEMOFIL M		26779, 26780, 50050, 26778	
ANTIHEMOPHILIC FACTOR/VWF	HUMATE-P		26449, 26451, 26450	
FACTOR IX RECOM,ALBUMIN FUSION	IDELVION		40749, 40751, 40752, 40753, 44859	
FACTOR IX HUMAN RECOMB,THR 148	IXINITY		38648, 38655, 43169, 43171, 43172, 38646	
FVIII REC,B-DOM DELET PEG-AUCL	JIVI		45218, 45219, 45221, 45222	
ANTIHEMOPHILIC FACTOR, HUMAN	KOATE-DVI		25132	
ANTIHEMOPHIL.FVIII,FULL LENGTH	KOGENATE FS		25136, 25127, 25130, 91942, 34917, 98833, 98831, 98832, 98764, 98634	
ANTIHEMOPHILIC FACTOR, HUMAN	MONOCLATE-P		9628	

FACTOR IX	MONONINE		91672	
MORPHINE SULFATE	MORPHINE SULFATE ER		16643, 16640, 16641, 16642, 16078	
ANTIHEMOPH.FVIII,B-DOM TRUNCAT	NOVOEIGHT		37395, 37396, 37397, 37393, 37398, 37394	
COAGULATION FACTOR VIIA,RECOMB	NOVOSEVEN RT		99696, 99697, 99698, 29034	
ANTIHEMOPH.FVIII,HEK B-DELETE	NUWIQ		38023, 38024, 38025, 38027, 43791, 43792, 43793, 37321	
INSULIN PUMP CARTRIDGE	OMNIPOD 5 PACK POD			NDC 08508-1120-05
INSULIN PUMP CARTRIDGE	OMNIPOD DASH 5 PACK POD			NDC 08508-2000-05
INSULIN PUMP CONTROLLER	OMNIPOD DASH PDM KIT			NDC 08508-2000-00
SUBCUTANEOUS INSULIN PUMP	OMNIPOD STARTER KIT			NDC 08508-1140-02
FACTOR IX CPLX(PCC)NO4,3FACTOR	PROFILNINE		25142, 25140, 25148	
TACROLIMUS	PROTOPIC		12302, 12289	
FACTOR IX HUMAN REC,PEGYLATED	REBINYN		43483, 43484, 43442	
ANTIHEMOPHILIC FACTOR, HUM REC	RECOMBINATE		25123, 25125, 25124, 26818	
FACTOR IX HUMAN RECOMBINANT	RIXUBIS		34869, 34873, 34874, 34875, 34868	

SEMAGLUTIDE	RYBELSUS		46964, 46965, 46966	
WETTING SOLN GAS,HARD AND SOFT	SYSTANE CONTACTS		94200	
FACTOR XIII A-SUBUNIT,RECOMB	TRETTEN		35833	
IBALIZUMAB-UIYK	TROGARZO		44504	
VON WILLEBRAND FACTOR	VONVENDI		40278, 40279	
ANTIHEMOPHILIC FACTOR/VWF	WILATE		32238, 32239	
RIVAROXABAN	XARELTO		36934, 30818, 30819, 14427, 37212	
ANTIHEMOPH.FVIII,B-DOMAIN DEL	XYNTHA, XYNTHA SOLOFUSE		9629, 9634, 29387, 31205, 31206, 30439, 30441	

GUIDELINES FOR USE

1. Is the request for an FDA approved (labeled) indication, or if the drug is requested for a non-FDA approved indication, does the patient have a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in two peer-reviewed medical literature articles, accepted standards of medical practice, or in one of the following compendia?
   - American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use
   - Clinical Pharmacology: Contains narrative text supporting use
   - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A
   - Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb
   - Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation

   If yes, **approve for the requested duration OR for a maximum of 12 months by HICL. The quantity approved must follow FDA dosing for the requested indication per package insert or be supported by compendia for non-FDA approved indications.**
   If no, do not approve.
   DENIAL TEXT: Use reason code G09.

RATIONALE
Ensure appropriate use of the identified medications.

Created: 12/19
Effective: 09/23/22 Client Approval: 09/15/22 P&T Approval: N/A

LONG ACTING INJECTABLE (LAI) ATYPICAL ANTIPSYCHOTICS (ILLINOIS MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
ARIPIPRAZOLE	ABILIFY MAINTENA		34284 34285 37681 37682	PREFERRED WITH PA
ARIPIPRAZOLE LAUROXIL	ARISTADA	42595		PREFERRED WITH PA
ARIPIPRAZOLE LAUROXIL,SUBMICR.	ARISTADA INITIO	45050		PREFERRED WITH PA
PALIPERIDONE PALMITATE	INVEGA SUSTENNA	36479		PREFERRED WITH PA
PALIPERIDONE PALMITATE	INVEGA TRINZA	36479		PREFERRED WITH PA
PALIPERIDONE PALMITATE	INVEGA HAFYERA	36479		NON-PREFERRED
RISPERIDONE MICROSPHERES	RISPERDAL CONSTA	25509		NON-PREFERRED
RISPERIDONE	PERSERIS		45127 45128	NON-PREFERRED
OLANZAPINE PAMOATE	ZYPREXA RELPREVV	36716		NON-PREFERRED

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of an FDA-approved indication for the requested agent and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older.
   - The diagnosis is schizophrenia, schizoaffective disorder, or bipolar 1 in accordance with the medication's specific FDA labeling.
   - The patient has documented one of the following:
     - History of nonadherence to oral antipsychotics **OR**
     - Stabilization on a LAI Atypical Antipsychotic while in a mental health facility
   - The patient has a documented oral tolerability of the active ingredient in the requested LAI, in accordance with the medication's specific FDA labeling.
   - The treatment regimen prescribed is not outside the medication's FDA labeling, and no contraindications or significant drug interactions to treatment exist.

   If yes, continue to #2.
   If no, do not approve. See the initial denial text on the next page.

CONTINUED ON NEXT PAGE

LONG ACTING INJECTABLE (LAI) ATYPICAL ANTIPSYCHOTICS (ILLINOIS MEDICAID)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **LONG ACTING INJECTABLE (LAI) ATYPICAL ANTIPSYCHOTICS** requires an FDA-approved indication. In addition, all of the following must be met:

- The patient is 18 years of age or older.
- The diagnosis is schizophrenia, schizoaffective disorder, or bipolar 1 in accordance with the medication's specific FDA labeling.
- The patient has documented one of the following:
  - History of nonadherence to oral antipsychotics **OR**
  - Stabilization on a LAI Atypical Antipsychotic while in a mental health facility
- The patient has a documented oral tolerability of the active ingredient in the requested LAI, in accordance with the medication's specific FDA labeling.
- The treatment regimen prescribed is not outside the medication's FDA labeling, and no contraindications or significant drug interactions to treatment exist.

2. Is the request for Invega Sustenna?

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient have established tolerability with oral paliperidone or oral risperidone?

   If yes, **approve INVEGA SUSTENNA for 12 months by GPID.**
   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **LONG ACTING INJECTABLE (LAI) ATYPICAL ANTIPSYCHOTICS** requires established tolerability with oral paliperidone or oral risperidone.

4. Is the request for Invega Trinza?

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient have a documented trial of Invega Sustenna of at least 4 months?

   If yes, **approve INVEGA TRINZA for 12 months by GPID.**
   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **LONG ACTING INJECTABLE (LAI) ATYPICAL ANTIPSYCHOTICS** requires a trial of Invega Sustenna of at least 4 months.

6. Is the request for any other preferred LAI?

   If yes, **approve for 12 months as follows:**
   - **ABILIFY MAINTENA all strengths by GPID**
   - **ARISTADA by HICL**
   - **ARISTADA INITIO by HICL**

   If no, continue to #7.

CONTINUED ON NEXT PAGE

LONG ACTING INJECTABLE (LAI) ATYPICAL ANTIPSYCHOTICS (ILLINOIS MEDICAID)

INITIAL CRITERIA (CONTINUED)

7. Does the patient have documented clinically significant treatment failure, intolerance, or contraindication to **preferred** LAI Atypical Antipsychotic agents?

   If yes, **approve for 12 months as follows:**
   - **INVEGA HAFYERA by GPID**
   - **RISPERDAL CONSTA by HICL**
   - **PERSERIS all strengths by GPID**
   - **ZYPREXA RELPREVV by HICL**

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **LONG ACTING INJECTABLE (LAI) ATYPICAL ANTIPSYCHOTICS** requires documented clinically significant treatment failure, intolerance, or contraindication to preferred Long Acting Injectable (LAI) Atypical Antipsychotic agents.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of an FDA-approved indication for the requested drugs and meet the following criteria?
   - Physician attestation that the patient is tolerating the requested medication.
   - The patient has a documented clinical response to the requested therapy.
   - The patient has had documented compliance with outpatient follow up appointments.

   If yes, **approve for 12 months as follows:**
   - **ABILIFY MAINTENA all strengths by GPID**
   - **ARISTADA by HICL**
   - **ARISTADA INITIO by HICL**
   - **INVEGA SUSTENNA by GPID**
   - **INVEGA TRINZA by GPID**
   - **INVEGA HAFYERA by GPID**
   - **RISPERDAL CONSTA by HICL**
   - **PERSERIS all strengths by GPID**
   - **ZYPREXA RELPREVV by HICL**

   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **LONG ACTING INJECTABLE (LAI) ATYPICAL ANTIPSYCHOTICS** requires an FDA-approved indication. In addition, all of the following must be met:
   - Physician attestation that the patient is tolerating the requested medication.
   - The patient has a documented clinical response to the requested therapy.
   - The patient has had documented compliance with outpatient follow up appointments.

CONTINUED ON NEXT PAGE

LONG ACTING INJECTABLE (LAI) ATYPICAL ANTIPSYCHOTICS (ILLINOIS MEDICAID)

RATIONALE

This prior authorization criteria is designed to promote appropriate utilization of LAI Atypical Antipsychotics in patients with repeated nonadherence to oral pharmacological treatment. Guidelines published by the American Psychiatric Association state that most patients with schizophrenia are at a very high risk for relapse in the absence of treatment.1 Patients with recurrent relapses related to partial or full nonadherence to oral treatment are candidates for LAI Atypical Antipsychotic medications. To ensure appropriate use of long-acting atypical antipsychotic agents are consistent with FDA-approved indications and Illinois Medicaid requirements.

See LAI Atypical Antipsychotic dosing guideline for information on individual agents.

Long-Acting Injectable (LAI) Atypical Antipsychotics Dosing Guide - 10.21.21

Medication and Dosage Form	FDA Indication / Minimum Patient age	Initial Dose	Maintenance Dose	Clinical Pearls
Preferred (with prior approval) Agents				

Abilify Maintena *(aripiprazole monohydrate)*
 	
ER powder for suspension in single-dose vial or pre-filled single-dose dual chamber syringes
 	
300 mg
400 mg
 	
IM injection: deltoid or gluteal
	Schizophrenia in adults (≥ 18 years)
	
	Maintenance monotherapy for **bipolar I** in adults (≥ 18 years)
	
	BBW: increased mortality in elderly patients with dementia-related psychosis
		400 mg IM
		
		Dose adjustments required for CYP2D6 poor metabolizers and those taking CYP3A4 inhibitors/inducers or CYP2D6 inhibitors
			400 mg IM once monthly
			
			Can be reduced to 300 mg IM for tolerability
			
			Give no sooner than 26 days after previous injection.
				• Establish tolerability with aripiprazole tablets before initiating ER IM injection. It may take up to 2 weeks to fully assess tolerability.
				• Oral aripiprazole (10 – 20 mg) or current antipsychotic medication should be given concurrently with the initial injection and should be continued for 14 consecutive days.
				• Do not confuse with short-acting aripiprazole injection (9.75mg/vial)
				• Missed Doses of Abilify Maintena
				  • Give the next dose of Abilify Maintena as soon as possible if:
				  • >4 and <5 weeks since dose 2 or 3
				  • >4 and <6 weeks since dose ≥4
				  • Restart Abilify Maintena AND bridge with 14 days of aripiprazole tablets if:
				  • >5 weeks since dose 2 or 3
				  • >6 weeks since dose ≥ 4

Aristada *(aripiprazole lauroxil)* ER suspension, single-dose prefilled syringe 441 mg 662 mg 882 mg 1064 mg	**Schizophrenia** in adults (≥ 18 years) BBW: increased mortality in elderly patients with dementia-related psychosis	Dosing based on total daily dose of oral aripiprazole. May start in 2 ways: 1. Initio 675mg loading dose + one dose of 30mg aripiprazole PO + Aristada IM 2. Aristada IM + 21 days of aripiprazole PO **Conversion Table** aripiprazole PO → Aristada IM	441 mg IM once monthly 662 mg IM once monthly 882 mg IM once monthly or every 6 weeks 1064 mg every 2 months Dose adjustments required by for CYP2D6 poor metabolizers or those taking CYP3A4	• Establish tolerability with aripiprazole tablets before initiating ER IM injection. It may take up to 2 weeks to fully assess tolerability. • Aristada should not be given earlier than 14 days after previous injection. • Missed Doses of Aristada • Restart Aristada therapy with Aristada Initio OR bridge with 7 days of aripiprazole PO:

<table>
<tr>
<td>IM injection: 441mg is deltoid or gluteal, other strengths gluteal only</td>
<td></td>
<td>10 mg/day

15 mg/day

⩾20 mg/ day</td>
<td>441 mg monthly

662 mg monthly 882 mg every 6 weeks 1064 mg every 2 months

882 mg monthly</td>
<td>inhibitors/inducers or CYP2D6 inhibitors</td>
<td>• >6 and ⩽7 weeks since 441 mg IM doses
• >8 and ⩽12 weeks since 662 mg or 882 mg IM doses
• >10 and ⩽12 weeks since 106 mg IM dose
• Restart Aristada therapy with Aristada Initio + one dose of 30mg aripiprazole PO OR bridge with 21 days of aripiprazole PO if:
• >7 weeks since 441 mg IM dose
• >12 weeks since 662 mg, 882 mg, or 1064 mg IM doses</td>
</tr>
<tr>
<td>Aristada Initio (aripiprazole lauroxil)

ER suspension, single-dose prefilled syringe

675 mg

IM injection: deltoid or gluteal</td>
<td>Schizophrenia in adults (⩾ 18 years)

BBW: increased mortality in elderly patients with dementia-related psychosis</td>
<td colspan="2">Used only as loading dose in combination with aripiprazole tablets and Aristada IM, not for repeat dosing.

To initiate Aristada therapy: Give 675mg Aristada Initio IM + one 30mg aripiprazole tablet + first dose of Aristada IM

To restart Aristada IM therapy after missed doses, Aristada Initio may be used. See above entry for Aristada.</td>
<td>Not applicable</td>
<td>• Establish tolerability with aripiprazole tablets before initiating ER IM injection. It may take up to 2 weeks to fully assess tolerability.
• Give Aristada injection on same day as Aristada Initio or up to 10 days later.
• Do not inject Aristada Initio and Aristada into the same muscle.
• Avoid use in CYP2D6 poor metabolizers or those taking strong CYP3A4 inhibitors/inducers or strong CYP2D6 inhibitors.
• Using Aristada Initio + 30mg aripiprazole + first dose Aristada will reach relevant aripiprazole concentrations within 4 days.
• Aristada Initio is not interchangeable with Aristada.</td>
</tr>
<tr>
<td>Invega Sustenna (paliperidone palmitate)

ER suspension, single-dose pre-filled syringe

39 mg
78 mg
117 mg
156 mg
234 mg

IM injection: deltoid or gluteal</td>
<td>Schizophrenia in adults (⩾ 18 years)

Schizoaffective disorder in adults (⩾ 18 years)

BBW: increased mortality in elderly patients with dementia-related psychosis</td>
<td colspan="2">Day 1: 234 mg IM
Day 8: 156 mg IM (+/- 4 days)

Doses on day 1 and day 8 are given in the deltoid, subsequent doses can be given in deltoid or glute)

Missed 2nd dose
• < 4 weeks since day 1, give 156mg IM ASAP, resume regular maintenance at 5 weeks from Day 1.
• 4 -7 weeks since day 1, give 156 mg IM ASAP, 156 mg IM dose 7 days later, wait 28 days and give 117 mg monthly.
• > 7 weeks since day 1, restart for treatment naïve patient (i.e. Day 1 234 mg IM, Day 8 156 mg IM, week 5 117 mg IM.)</td>
<td>Starting 5 weeks after first injection, given monthly (+/- 7 days).

Monthly dose is based on diagnosis, tolerability, and efficacy.

Schizophrenia: range is 39 mg to 234 mg, but recommended dose is 117 mg

Schizoaffective disorder: range is 78 mg to 234 mg

Conversion table
Paliperidone PO | Sustenna IM
12 mg/day | 234 mg/month
9 mg/day | 156 mg/month
6 mg/day | 117 mg/month
3 mg/day | 39-78 mg/month</td>
<td>• Establish tolerability with oral paliperidone or risperidone before initiating Invega Sustenna. Options per clinical trials:
• Paliperidone ER 3 mg/day for ⩾2 consecutive days
• Paliperidone ER 3 mg/day or risperidone 1 mg/day for at least 28 or 3 days
• Paliperidone ER for 4 days at a dose of 3 mg/day
• Paliperidone ER 6 mg/day for 4-6 days
• Oral AAP should be discontinued with initiation of IM formulation.
• Alternate deltoid injections.
• Renal Impairment
• CrCl 50 to 80 mL/min dose adjust to Day 1: 156 mg, Day 89 117 mg, and 78 mg for maintenance
• Not recommended if CrCl < 50 ml/min</td>
</tr>
</table>

<table>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>

Avoid use of Invega Sustenna with strong CYP3A4/P-glycoprotein (P-gp) inducers.
Missed maintenance doses of Invega Sustenna

4 - 6 weeks since last dose, resume ASAP
>6 weeks to < 6 months since last dose resume previous dose ASAP (except 234 mg)
If stable on 234mg, give 156 mg IM ASAP followed by 156 mg 7 days later, wait 28 days and resume 234 mg IM
>6 months since last dose, restart therapy as treatment naïve patient.

Higher Cmax attained following deltoid injection versus gluteal injection. Longer half-life following gluteal injection versus deltoid injection. Recommend gluteal injection for providers requesting q 3 week administration.

</td>
</tr>
<tr>
<td>Invega Trinza
(paliperidone palmitate)

ER Suspension, single-dose pre-filled syringe
273 mg
410 mg
546 mg
819 mg

IM injection: deltoid or gluteal</td>
<td>Schizophrenia in adults (⩾ 18 years)

BBW: increased mortality in elderly patients with dementia-related psychosis</td>
<td>Start Invega Trinza only after ⩾ 4 months of adequate treatment on Invega Sustenna.

PI recommends that the last 2 doses of Invega Sustenna be the same strength before starting Trinza.

Give the first dose of Trinza in place of the next scheduled dose of Invega Sustenna (+/- 7 days).

Dosing based on equivalent 3.5x higher dose.

Conversion Table
<table>
<tr><th>Sustenna</th><th>Trinza</th></tr>
<tr><td>78 mg</td><td>273 mg</td></tr>
<tr><td>117 mg</td><td>410 mg</td></tr>
<tr><td>156 mg</td><td>546 mg</td></tr>
<tr><td>234 mg</td><td>819 mg</td></tr>
</table>
</td>
<td colspan="2">IM dosing every 3 months (+/- 14 days)

Dose adjustments made based on efficacy and tolerability.

Due to long half-life response to dose adjustment may not be apparent for several months.</td>
<td>

Missed doses of Invega Trinza

3.5-4 months since last dose, give Trinza ASAP, then resume 3-month dosing schedule.
4-9 months since last dose, re-initiate equivalent Invega Sustenna dose on Day 1 and Day 8, then wait 28 days and resume Trinza.
>9 months since last dose, re-initiate as treatment naïve for Invega Sustenna. See instructions above. Patient must have ⩾4 months of adequate treatment with Sustenna before resuming Trinza.

Renal Impairment

CrCl 50 to 80 mL/min dose adjust Invega Sustenna and transition to equivalent dose of Trinza.
Not recommended if CrCl < 50 ml/min

Avoid use of Invega Trinza with strong CYP3A4/P-glycoprotein (P-gp) inducers.
Oral AAP should be discontinued with initiation of all IM paliperidone formulations.
Longer half-life following gluteal injection versus deltoid injection. Recommend gluteal injection for providers requesting administration < every 3 months.

</td>
</tr>
<tr><td colspan="6">Non-Preferred Agents</td></tr>
</table>

<table>
<tr>
<td>Invega Hafyera
(paliperidone palmitate)

ER Suspension, single-dose pre-filled syringe

1092 mg
1560 mg

IM injection: gluteal</td>
<td>Schizophrenia in adults (≥ 18 years)

BBW: increased mortality in elderly patients with dementia-related psychosis</td>
<td>Start Hafyera only after:
1) trial of Sustenna ≥4 months
2) trial of Trinza for ≥1 3-month cycle

<table>
<tr><td colspan="2">Conversion Table</td></tr>
<tr><td>Sustenna*</td><td>Hafyera</td></tr>
<tr><td>156 mg</td><td>1092 mg</td></tr>
<tr><td>234 mg</td><td>1560 mg</td></tr>
<tr><td>Trinza*</td><td>Hafyera</td></tr>
<tr><td>564 mg</td><td>1092 mg</td></tr>
<tr><td>819 mg</td><td>1560 mg</td></tr>
</table>
*other doses not studied for switching.</td>
<td>IM dosing to gluteal muscle every 6 months (-14 days to +21 days)

Dose adjustments made based on efficacy and tolerability.

Due to long half-life response to dose adjustment may not be apparent for several months.</td>
<td>• Invega Hafyera can only be administered to the gluteal muscle.
• Give the first dose of Hafyera in place of the next scheduled dose of Invega Sustenna (+/- 7 days); the previous 2 doses of Sustenna be the same strength before starting Hafyera.
• Give the first dose of Hafyera in place of the next scheduled dose of Invega Trinza (+/-14 days)
• Avoid use of Invega Hafyera with strong CYP3A4/P-glycoprotein (P-gp) inducers.
• Renal Impairment
  • CrCl 50 to 80 mL/min dose adjust Invega Sustenna and transition to equivalent dose of Trinza.
  • Not recommended if CrCl < 50 ml/min
• Missed doses of Invega Hafyera
  • 6.75-8 months since last dose give Sustenna Day 1 and Invega Hafyera Day 29. Dosing is Sustenna 156 mg for Hafyera 1092 mg or Sustenna 234mg for Hafyear 1560 mg.
  • 8-11 months since last dose. Give Sustenna 156mg on Day 1 and Day 8, wait 28 days and give Hafyera 1092 mg or 1560 mg.
  • >11 months since last dose, do not give Hafyera. Restart as if treatment naïve with Invega Sustenna.</td>
</tr>
<tr>
<td>Risperdal Consta
(risperidone)

ER powder for suspension, vial kits
12.5 mg
25 mg
37.5 mg
50 mg

IM injection: deltoid or gluteal</td>
<td>Schizophrenia in adults (≥ 18 years)

Maintenance monotherapy or as adjunct to lithium or valproate for bipolar I in adults (≥ 18 years)

BBW: increased mortality in elderly patients with dementia-related psychosis</td>
<td>Use 25mg dose for most patients

Use 12.5 mg for geriatric patients or those with poor renal/hepatic function, but efficacy has not been studied at this dose.</td>
<td>IM dosing every 2 weeks.

No recommendations on earliest time to next dose.

Dose adjustments made based on efficacy and tolerability.

Wait 4 weeks between each dose escalation.</td>
<td>• Establish tolerability to oral risperidone before initiating with long-acting IM injection.
• Oral risperidone or another AAP should be given with the first Consta injection and should be continued for 3 weeks of therapy and then discontinued.
• Clinical effects of dose adjustment should not be expected earlier than 3 weeks after the injection of the higher dose
• No data for missed doses. Restart Consta with oral risperidone for 3 weeks.
• Use of concurrent CYP3A4 inducers and CYP2D6 inhibitors will result in altered concentrations of risperidone.</td>
</tr>
<tr>
<td>Perseris
(risperidone)

ER powder for suspension, syringe kits

90 mg</td>
<td>Schizophrenia in adults (≥ 18 years)

BBW: increased mortality in elderly patients with</td>
<td>May start either dose. See table below for equivalency.

Equivalent Plasma Concentrations</td>
<td>Monthly subcutaneous injection into abdomen.

No recommendations on earliest time to next dose.</td>
<td>• Establish tolerability to oral risperidone. Patients stable on < 3mg/day or higher than 4 mg/day may not be good candidates for Perseris.
• Do not supplement Perseris with oral risperidone or another AAP.</td>
</tr>
</table>

<table>
<tr>
<td>120 mg

Subcutaneous: abdomen</td>
<td>dementia-related psychosis</td>
<td colspan="2"><table>
<tr><td>Risperidone PO</td><td>Perseris</td></tr>
<tr><td>3 mg/day</td><td>90 mg/month</td></tr>
<tr><td>4 mg/day</td><td>120 mg/month</td></tr>
</table></td>
<td></td>
<td>• Use of concurrent CYP3A4 inducers and CYP2D6 inhibitors will result in altered concentrations of risperidone.
• For missed doses of Perseris. give next dose ASAP.
• Patients with hepatic or renal impairment, must be safely titrated to ⩾3 mg/day of risperidone PO before considering Perseris 90 mg.</td>
</tr>
<tr>
<td>Zyprexa Relprevv (olanzapine pamoate)

ER powder for suspension
210 mg
300 mg
405 mg

IM injection: gluteal</td>
<td>Schizophrenia in adults (⩾ 18 years)

BBW: Post-injections delirium/sedation syndrome, increased mortality in elderly patients with dementia-related psychosis</td>
<td colspan="2">Dosing for weeks 1 to 8 based on conversion table below.
No recommendations on earliest time to next dose.

<table>
<tr><td colspan="2">Conversion Table Week 1 - 8</td></tr>
<tr><td>Olanzapine PO</td><td>IM</td></tr>
<tr><td>10 mg/day</td><td>210 mg/2 weeks or 405 mg/4 weeks</td></tr>
<tr><td>15 mg/day</td><td>300 mg/2 weeks</td></tr>
<tr><td>20 mg/day</td><td>300 mg/2 weeks</td></tr>
</table></td>
<td>Maintenance dosing after week 8.
No recommendations for missed doses.

<table>
<tr><td>Maintenance after week 8</td></tr>
<tr><td>IM</td></tr>
<tr><td>150 mg/ 2 weeks or 300 mg/4 weeks</td></tr>
<tr><td>210 mg/2 weeks or 405 mg/4 weeks</td></tr>
<tr><td>300 mg/2 weeks</td></tr>
</table></td>
<td>• Establish tolerability with oral olanzapine before initiating ER IM injection. No Data for switching from other AAP available.
• Plasma concentrations after switch to Zyprexa Relprevv may require treatment of 3 months to reestablish steady-state conditions.
• For deep IM gluteal injection only.
• For debilitated patients, those with predisposition to hypotensive reactions, slow metabolizers of olanzapine, or those pharmacodynamically sensitive to olanzapine the recommended starting dose is 150 mg/4 weeks.
• Do not confuse the short-acting formulation (Zyprexa IM 10 mg/vial) with the ER suspension Zyprexa Relprevv (olanzapine pamoate)
• REMS enrollment required due risk of post-injection delirium/sedation syndrome; patient must be observed for ⩾3 hours post-injection with Relprevv.</td>
</tr>
</table>

AAP atypical antipsychotics, *ER* extended-release, *FDA* United States Food and Drug Administration, *IM* intramuscular, *PO* by mouth

REFERENCES

1. American Psychiatric Association. Practice guidelines for the treatment of patients with schizophrenia – Third Edition. September 2020. Available at: https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890424841. Accessed October 22, 2021.
2. Abilify Maintena. Package insert. Otsuka Pharmaceutical Co., Ltd.; 2020.
3. Aristada. Package insert. Alkermes, Inc.; 2020.
4. Aristada Initio. Package insert. Alkermes, Inc.; 2020.
5. Invega Sustenna. Package insert. Janssen Pharmaceuticals, Inc.; 2021.
6. Invega Trinza. Package insert. Janssen Pharmaceuticals, Inc.; 2021.
7. Invega Hafyera. Package insert. Janssen Pharmaceuticals, Inc.; 2021.
8. Risperdal Consta. Package insert. Janssen Pharmaceuticals, Inc.; 2021.
9. Perseris. Package insert. Indivior, Inc.; 2019.
10. Zyprexa Relprevv. Package insert. Eli Lilly; 2019.

Created: 03/19
Effective: 09/16/22 Client Approval: 09/06/22 P&T Approval: N/A

ONASEMNOGENE ABEPARVOVEC-XIOI (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ONASEMNOGENE ABEPARVOVEC-XIOI	ZOLGENSMA	45760		

GUIDELINES FOR USE

Zolgensma (onasemnogene abeparvovec-xioi), is not covered under the pharmacy benefit. It may be covered under medical. Do not review requests.

DENIAL TEXT: Zolgensma (onasemnogene abeparvovec-xioi), is not covered under the pharmacy benefit. Please submit for consideration under the medical benefit. Contact information can be found on your medical benefit ID card.

Created: 06/19
Effective: 06/17/19 Client Approval: N/A P&T Approval: N/A

COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

PROTON PUMP INHIBITORS (ILLINOIS MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
DEXLANSOPRAZOLE	DEXILANT	36085		
ESOMEPRAZOLE	NEXIUM	21607		
LANSOPRAZOLE	PREVACID	08993		
OMEPRAZOLE	PRILOSEC	04673 11115		
PANTOPRAZOLE	PROTONIX	11590		
RABERPRAZOLE	ACIPHEX	18847		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a PPI age restriction override?

   If yes, continue to #2.
   If no, this guideline does not apply.

2. Is the request for a PPI that is preferred on the Illinois State PDL?

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet one of the below criteria?
   - The patient is under the care of a Gastroenterologist **OR**
   - The patient has one of the following conditions: GI bleed, Erosive Esophagitis, Pathological Hypersecretory Syndrome, Unhealed Gastric, Duodenal or Peptic Ulcer, Barret's Esophagus, Zollinger-Ellison Syndrome, or Helicobacter pylori infection

   If yes, **approve for 90 days by HICL.**
   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **PROTON PUMP INHIBITORS** requires the patient be under the care of a Gastroenterologist or have a GI bleed, Erosive Esophagitis, Pathological Hypersecretory Syndrome, Unhealed Gastric, Duodenal or Peptic Ulcer, Barret's Esophagus, Zollinger-Ellison Syndrome, or Helicobacter pylori infection.

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PROTON PUMP INHIBITORS (ILLINOIS MEDICAID)

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet all of the below criteria for non-preferred Illinois State PDL PPI requests?
   - The patient must have at least a 90-day history of at least **two** PDL preferred PPIs **AND**
   - Member is under the care of a Gastroenterologist **OR**
   - The patient has one of the following conditions: GI bleed, Erosive Esophagitis, Pathological Hypersecretory Syndrome, Unhealed Gastric, Duodenal or Peptic Ulcer, Barret's Esophagus, Zollinger-Ellison Syndrome, or Helicobacter pylori infection

   If yes, **approve for 90 days by HICL.**
   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **PROTON PUMP INHIBITORS** requires the patient to have at least a 90-day history of at least two PDL preferred PPIs. In addition, the patient must be under the care of a Gastroenterologist OR have a GI bleed, Erosive Esophagitis, Pathological Hypersecretory Syndrome, Unhealed Gastric, Duodenal or Peptic Ulcer, Barret's Esophagus, Zollinger-Ellison Syndrome, or Helicobacter pylori infection.

RENEWAL CRITERIA

1. Is the request for a PPI age restriction override?

   If yes, continue to #2.
   If no, this guideline does not apply.

2. Does the patient meet one of the below criteria?
   - The patient is under the care of a Gastroenterologist **OR**
   - The patient has one of the following conditions: GI bleed, Erosive Esophagitis, Pathological Hypersecretory Syndrome, Unhealed Gastric, Duodenal or Peptic Ulcer, Barret's Esophagus, or Zollinger-Ellison Syndrome.

   If yes, **approve for 1 YEAR by HICL.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **PROTON PUMP INHIBITORS** requires the patient to be under the care of a Gastroenterologist OR have a GI bleed, Erosive Esophagitis, Pathological Hypersecretory Syndrome, Unhealed Gastric, Duodenal or Peptic Ulcer, Barret's Esophagus, or Zollinger-Ellison Syndrome.

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PROTON PUMP INHIBITORS (ILLINOIS MEDICAID)

RATIONALE

To ensure appropriate use of proton pump inhibitors consistent with the IL state PDL. The IL state PDL requires clinical review for members of certain age requesting PPI therapy.

REFERENCES

- AstraZeneca Pharmaceuticals LP, Nexium Package Insert. Wilmington, DE. March 2018
- AstraZeneca Pharmaceutical LP, Prilosec Package Insert. Wilmington, DE. March 2018
- Eisai, Inc. Aciphex Package Insert. Woodcliff Lake, NJ September 2019
- https://www.ncbi.nlm.nih.gov
- https://reference.medscape.com/drugs/protonpumpinhibitors.
- Takeda Pharmaceuticals America, Inc. Prevacid Package Insert. Deerfield, IL October 2018
- Takeda Pharmaceuticals America, Inc. Dexilant Package Insert. Deerfield, IL November 2019
- Wyeth Pharmaceuticals Inc. Protonix Package Insert. Philadelphia, PA. December 2019
- Santarus, Inc. Zegerid Package Insert. San Diego. September 2019

Created: 03/20
Effective: 05/01/20 Client Approval: 03/18/20 P&T Approval: N/A

SOMATROPIN

Generic	Brand	HICL	GCN	Exception/Other
SOMATROPIN	GENOTROPIN, HUMATROPE, NORDITROPIN FLEXPRO, NUTROPIN AQ, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, SEROSTIM, ZOMACTON, ZORBTIVE	02824		

GUIDELINES FOR USE

NOTE: Please use the criteria for the specific drug requested.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

SEROSTIM

1. Is the request for Serostim for a patient with a diagnosis of HIV wasting/cachexia and meet **ALL** of the following criteria?
   - The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
   - The medication is prescribed by or in consultation with one of the following specialist: Gastroenterologist, Nutritional Support Specialist OR Infectious Disease Specialist
   - The patient is on HIV anti-retroviral therapy
   - The patient has inadequate response to previous therapy (i.e., exercise training, nutritional supplements, appetite stimulants or anabolic steroids)
   - The patient has an inadequate response to previous pharmacological therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
   - Alternative causes of wasting has been ruled out. Alternative causes include:
     - Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
     - Diarrhea
     - Inadequate energy (caloric) intake
     - Malignancies
     - Opportunistic infections
   - The patient meets **ONE** of the following criteria for weight loss:
     - 10% unintentional weight loss over 12 months
     - 7.5% unintentional weight loss over 6 months
     - 5% body cell mass (BCM) loss within 6 months
     - BCM less than 35% (men) **AND** a body mass index (BMI) less than 27 kg per meter squared
     - BCM less than 23% (women) of total body weight **AND** a body mass index (BMI) less than 27 kg per meter squared
     - BMI less than 18.5 kg per meter squared

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **SEROSTIM** guideline.

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SOMATROPIN

INITIAL CRITERIA - SEROSTIM (CONTINUED)

2. Is the patient hypogonadal as defined by **ONE** of the following?
   - Total serum testosterone level of less than 300ng/dL (10.4 nmol/L)
   - A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
   - A free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

   If yes, continue to #3.
   If no, **approve Serostim for 12 weeks by GPID.**

3. For patients who are hypogonadal, does the patient meet the following criteria?
   - The patient has tried testosterone therapy (examples include testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

   If yes, **approve Serostim for 12 weeks by GPID.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **SEROSTIM** guideline.

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SOMATROPIN

INITIAL CRITERIA - SEROSTIM (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Serostim)** requires a diagnosis of HIV wasting/cachexia. The following criteria must also be met.

- The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
- The medication is prescribed by or in consultation with one of the following specialist: Gastroenterologist, Nutritional Support Specialist OR Infectious Disease Specialist
- The patient is on HIV anti-retroviral therapy
- The patient has an inadequate response to previous therapy (i.e., exercise training, nutritional supplements, appetite stimulants or anabolic steroids)
- The patient has an inadequate response to previous pharmacological therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
- Alternative causes of wasting have been ruled out. Alternative causes include:
  - Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
  - Diarrhea
  - Inadequate energy (caloric) intake
  - Malignancies
  - Opportunistic infections
- The patient meets **ONE** of the following criteria for weight loss:
  - 10% unintentional weight loss over 12 months
  - 7.5% unintentional weight loss over 6 months
  - 5% body cell mass (BCM) loss within 6 months
  - BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
  - BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
  - BMI less than 18.5 kg per meter squared

The following criteria must also be met.

- **For patients who are hypogonadal (patients with low testosterone levels)**, **approval requires the following:**
  - The patient has tried testosterone therapy (examples include testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)
  - The patient meets one of the following criteria for low testosterone:
    - Total serum testosterone level of less than 300ng/dL (10.4nmol/L)
    - A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
    - A free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

ZORBTIVE

1. Is the request for Zorbtive for a patient with a diagnosis of short bowel syndrome and meet the following criteria?
   - The requested agent requested is **NOT** prescribed for athletic enhancement or anti-aging purposes
   - The patient is currently on specialized nutritional support (such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)
   - The medication is prescribed by or in consultation with a gastroenterologist

   If yes, **approve Zorbtive for 4 weeks by GPID for #1 vial per day (max dose not to exceed 8mg per day).**
   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Zorbtive)** requires a diagnosis of short bowel syndrome. The following criteria must also be met:
   - The requested agent requested is **NOT** prescribed for athletic enhancement or anti-aging purposes
   - The patient is currently on specialized nutritional support (such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)
   - The medication is prescribed by or in consultation with a gastroenterologist

GENOTROPIN

1. Is the request for Genotropin for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **GENOTROPIN** guideline.
   If no, continue to #2.

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SOMATROPIN

INITIAL CRITERIA - GENOTROPIN (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meet **ALL** of the associated criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - The patient meets at least **ONE** of the following criteria for short stature:
       - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
       - Height velocity less than the 25th percentile for age
       - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender
   - **For the diagnosis of growth failure associated with Turner Syndrome, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
   - **For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), approval requires:**
     - Confirmed genetic diagnosis of PWS
     - The medication is prescribed by or in consultation with an endocrinologist
   - **For the diagnosis of growth failure due in children born small for gestational age (SGA), approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Patient with no catch-up growth by age 2 years
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
   - **For the diagnosis of adult growth hormone deficiency**, **approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

   If yes, **approve Genotropin for 12 months by GPID.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **GENOTROPIN** guideline.

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SOMATROPIN

INITIAL CRITERIA - GENOTROPIN (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Genotropin)** requires one of the following diagnoses:

- Pediatric growth hormone deficiency (GHD)
- Growth failure associated with Turner syndrome
- Growth failure due to Prader-Willi syndrome (PWS)
- Growth failure in children born small for gestational age (SGA)
- Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

- **For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - The patient meets at least **ONE** of the following criteria for short stature:
    - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
    - Height velocity less than the 25^{th} percentile for age
    - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender
- **For the diagnosis of growth failure associated with Turner syndrome, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
- **For the diagnosis of growth failure due to Prader-Willi syndrome (PWS), approval requires:**
  - Confirmed genetic diagnosis of PWS
  - The medication is prescribed by or in consultation with an endocrinologist
- **For the diagnosis of growth failure in children born small for gestational age (SGA)**, **approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Patient with no catch-up growth by age 2 years
  - Patient’s height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

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SOMATROPIN

INITIAL CRITERIA - GENOTROPIN (CONTINUED)

- **For the diagnosis of adult growth hormone deficiency, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

HUMATROPE

1. Is the request for Humatrope for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **HUMATROPE** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and has met the following criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - The patient meets at least **ONE** of the following criteria for short stature:
       - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
       - Height velocity less than the 25^{th} percentile for age
       - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender
   - **For the diagnosis of short stature associated with Turner Syndrome, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
   - **For the diagnosis of short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Patient’s height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

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SOMATROPIN

INITIAL CRITERIA - HUMATROPE (CONTINUED)

- **For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Patient with no catch-up growth by age 2 to 4 years
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
- **For the diagnosis of adult growth hormone deficiency, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

If yes, **approve Humatrope for 12 months by GPID.**
If no, do not approve.
INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Humatrope)** requires one of the following diagnoses:

- Pediatric growth hormone deficiency
- Short stature associated with Turner Syndrome
- Short stature or growth failure in short stature homeobox-containing gene(SHOX) deficiency
- Growth failure in children born small for gestational age (SGA)
- Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

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SOMATROPIN (MANAGED MEDICAID)

INITIAL CRITERIA - HUMATROPE (CONTINUED)

The following criteria must also be met.

- **For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - The patient meets at least **ONE** of the following criteria for short stature:
    - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
    - Height velocity less than the 25th percentile for age
    - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender
- **For the diagnosis of short stature associated with Turner Syndrome, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses is **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
- **For the diagnosis of short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses is **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
- **For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:**
  - The medication is prescribed by on in consultation with an endocrinologist
  - The patient's epiphyses is **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Patient with no catch-up growth by age 2 to 4 years
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
- **For the diagnosis of adult growth hormone deficiency, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

NORDITROPIN FLEXPRO

1. Is the request for Norditropin FlexPro for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **NORDITROPIN FLEXPRO** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - The patient meets at least **ONE** of the following criteria for short stature:
       - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
       - Height velocity less than the 25^{th} percentile for age
       - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender
   - **For the diagnosis of short stature associated with Turner Syndrome, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
   - **For the diagnosis of short stature associated with Noonan Syndrome, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
   - **For the diagnosis of short stature born small for gestational age (SGA) in a pediatric patient, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Patient with no catch-up growth by age 2 to 4 years
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

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SOMATROPIN

INITIAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

- **For the diagnosis of adult growth hormone deficiency, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
- **For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), approval requires:**
  - Confirmed genetic diagnosis of PWS
  - The medication is prescribed by or in consultation with an endocrinologist

If yes, **approve Norditropin FlexPro for 12 months by GPID.**
If no, do not approve.
INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Norditropin FlexPro)** requires one of the following diagnoses:

- Pediatric growth hormone deficiency (GHD)
- Short stature associated with Turner Syndrome
- Short stature associated with Noonan Syndrome
- Short stature born small for gestational age (SGA) in a pediatric patient
- Adult growth hormone deficiency
- Growth failure due to Prader-Willi syndrome (PWS)

This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

- **For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - The patient meets at least **ONE** of the following criteria for short stature:
    - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
    - Height velocity less than the 25^{th} percentile for age
    - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender

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SOMATROPIN

INITIAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

- **For the diagnosis of diagnosis of short stature associated with Turner Syndrome, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
- **For the diagnosis of short stature associated with Noonan Syndrome, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
- **For the diagnosis of short stature born small for gestational age (SGA) in a pediatric patient, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Patient with no catch-up growth by age 2 to 4 years
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
- **For the diagnosis of adult growth hormone deficiency, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
- **For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), approval requires:**
  - Confirmed genetic diagnosis of PWS
  - The medication is prescribed by or in consultation with an endocrinologist

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

NUTROPIN AQ, NUTROPIN AQ NUSPIN

1. Is the request for Nutropin AQ or Nutropin AQ NuSpin for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **NUTROPIN AQ and NUTROPIN AQ NUSPIN** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - The patient meets at least **ONE** of the following criteria for short stature:
       - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
       - Height velocity less than the 25th percentile for age
       - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender
   - **For the diagnosis of growth failure secondary to chronic kidney disease (CKD), approval requires:**
     - The medication is prescribed by or in consultation with a nephrologist
     - The patient has **NOT** undergone a renal transplantation
     - Patient's height or growth velocity greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
   - **For the diagnosis of short stature associated with Turner Syndrome, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses is **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
   - **For the diagnosis of adult growth hormone deficiency, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

   If yes, **approve Nutropin AQ or Nutropin AQ NuSpin for 12 months by GPID.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **NUTROPIN AQ and NUTROPIN AQ NUSPIN** guideline.

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SOMATROPIN

INITIAL CRITERIA - NUTROPIN AQ, NUTROPIN AQ NUSPIN (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Nutropin AQ, Nutropin AQ NuSpin)** requires one of the following diagnoses:

- Pediatric growth hormone deficiency (GHD)
- Growth failure secondary to chronic kidney disease (CKD)
- Short stature associated with Turner Syndrome
- Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

- **For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - The patient meets at least **ONE** of the following criteria for short stature:
    - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
    - Height velocity less than the 25^{th} percentile for age
    - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender
- **For the diagnosis of growth failure secondary to chronic kidney disease (CKD), approval requires:**
  - The patient has not undergone a renal transplantation
  - The medication is prescribed by or in consultation with a nephrologist
  - Patient's height or growth velocity greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
- **For the diagnosis of short stature associated with Turner Syndrome, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses is **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
- **For the diagnosis of adult growth hormone deficiency, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

OMNITROPE

1. Is the request for Omnitrope for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **OMNITROPE** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - The patient meets at least **ONE** of the following criteria for short stature:
       - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
       - Height velocity less than the 25^{th} percentile for age
       - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender
   - **For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), approval requires:**
     - Confirmed genetic diagnosis of PWS
     - The medication is prescribed by or in consultation with an endocrinologist
   - **For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:**
     - Patient with no catch-up growth by age 2 years
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
   - **For the diagnosis of growth failure associated with Turner Syndrome, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
   - **For the diagnosis of adult growth hormone deficiency, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

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INITIAL CRITERIA - OMNITROPE (CONTINUED)

If yes, **approve Omnitrope for 12 months by GPID.**
If no, do no approve.
INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Omnitrope)** requires one of the following diagnoses:

- Pediatric growth hormone deficiency (GHD)
- Growth failure due to Prader-Willi Syndrome (PWS)
- Growth failure in children born small for gestational age (SGA)
- Growth failure associated with Turner Syndrome
- Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

- **For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - The patient meets at least **ONE** of the following criteria for short stature:
    - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
    - Height velocity less than the 25th percentile for age
    - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender
- **For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), approval requires:**
  - Confirmed genetic diagnosis of PWS
  - The medication is prescribed by or in consultation with an endocrinologist
- **For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:**
  - Patient with no catch-up growth by age 2 years
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

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SOMATROPIN

INITIAL CRITERIA - OMNITROPE (CONTINUED)

- **For the diagnosis of growth failure associated with Turner Syndrome, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses is **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
- **For the diagnosis of adult growth hormone deficiency, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

SAIZEN

1. Is the request for Saizen for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **SAIZEN** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - The patient meets at least **ONE** of the following criteria for short stature:
       - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
       - Height velocity less than the 25th percentile for age
       - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender
   - **For the diagnosis of adult growth hormone deficiency, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

   If yes, **approve Saizen for 12 months by GPID.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **SAIZEN** guideline.

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SOMATROPIN

INITIAL CRITERIA - SAIZEN (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Saizen)** requires one of the following diagnoses:

- Pediatric Growth Hormone Deficiency (GHD)
- Adult Growth Hormone Deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

- **For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - The patient meets at least **ONE** of the following criteria for short stature:
    - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
    - Height velocity less than the 25th percentile for age
    - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender
- **For the diagnosis of adult growth hormone deficiency, approval requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

ZOMACTON (formulary called TEV-TROPIN)

1. Is the request for Zomacton for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **ZOMACTON** guideline.
   If no, continue to #2.

CONTINUED ON NEXT PAGE

SOMATROPIN

INITIAL CRITERIA - ZOMACTON (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - The patient meets at least **ONE** of the following criteria for short stature:
       - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
       - Height velocity less than the 25th percentile for age
       - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender
   - **For the diagnosis of short stature associated with Turner Syndrome, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
   - **For the diagnosis of short stature in children born small for gestational age (SGA)**, **approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Patient with no catch-up growth by age 2 to 4 years
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
   - **For the diagnosis of short stature or growth failure in children with SHOX deficiency, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
   - **For the diagnosis of adult growth hormone deficiency, approval requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

   If yes, **approve Zomacton for 12 months by GPID.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **ZOMACTON** guideline.

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SOMATROPIN

INITIAL CRITERIA - ZOMACTON (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Zomacton)** requires one of the following diagnoses:

- Pediatric Growth Hormone Deficiency (GHD)
- Short stature associated with Turner Syndrome
- Short stature in children born small for gestational age (SGA)
- Short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency
- Adult Growth Hormone Deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:

- The medication is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses is **NOT** closed (as confirmed by radiograph of the wrist and hand)
- The patient meets at least **ONE** of the following criteria for short stature:
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
  - Height velocity less than the 25th percentile for age
  - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender

For the diagnosis of short stature associated with Turner Syndrome, approval requires:

- The medication is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
- Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

For the diagnosis of short stature in children born small for gestational age (SGA), **approval requires:**

- The medication is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
- Patient with no catch-up growth by age 2 to 4 years
- Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

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SOMATROPIN

INITIAL CRITERIA - ZOMACTON (CONTINUED)

For the diagnosis of short stature or growth failure in children with SHOX deficiency, approval requires:

- The medication is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
- Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

For the diagnosis of adult growth hormone deficiency, approval requires:

- The medication is prescribed by or in consultation with an endocrinologist
- The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

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SOMATROPIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

SEROSTIM

1. Has the patient received more than 24 weeks of therapy within plan year?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **SEROSTIM** guideline.
   If no, continue to #2.

2. Is the request for Serostim for a patient with HIV wasting/cachexia and meet the following criteria?
   - The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
   - The patient has shown clinical benefit in muscle mass and weight as indicated by the following criteria:
     - ≥ 10% increase in weight or BCM from baseline (**Note**: current and baseline weight must be documented including dates of measurement)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **SEROSTIM** guideline.

3. Is the patient on HIV anti-retroviral therapy?

   If yes, **approve Serostim for 12 weeks by GPID.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Serostim)** renewal requires a diagnosis of HIV wasting/cachexia. The following criteria must be met:
   - The patient has **NOT** received more than 24 weeks of therapy within the plan year
   - The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
   - The patient has shown clinical benefit in muscle mass and weight as indicated by the following criteria:
     - ≥ 10% increase in weight or BCM from baseline (**Note**: current and baseline weight must be documented including dates of measurement)
   - Patient must be on HIV anti-retroviral therapy

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

ZORBTIVE

1. Does the patient have a diagnosis of short bowel syndrome?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **ZORBTIVE** guideline.

2. Has the patient been on the medication for 4 weeks?

   If yes, do not approve. [**Note:** The patient should only be approved for one 4 week fill in a lifetime.]
   RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Zorbtive)** renewal requires a diagnosis of short bowel syndrome. Therapy is limited to 4 weeks of treatment.

   If no, **approve Zorbtive by GPID for the remainder of therapy with a maximum of 4 weeks of therapy (Please subtract any previous fills, maximum cumulative approval is for 4 weeks).**

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

GENOTROPIN

1. Is the request for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **GENOTROPIN** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of short stature associated with Turner Syndrome, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - Improvement in body composition
   - **For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of adult growth hormone deficiency, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist

   If yes, **approve Genotropin for 12 months by GPID.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **GENOTROPIN** guideline.

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SOMATROPIN

RENEWAL CRITERIA - GENOTROPIN (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Genotropin)** renewal requires a diagnosis of Pediatric Growth Hormone Deficiency (GHD), Short Stature Associated with Turner Syndrome, Growth Failure Due to Prader-Willi Syndrome (PWS), Growth failure in children born small for gestational age (SGA), or Adult Growth Hormone Deficiency.

This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

- **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses is **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
- **For the diagnosis of short stature associated with Turner Syndrome, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses is **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
- **For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - Improvement in body composition
- **For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses is **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
- **For the diagnosis of adult growth hormone deficiency, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

HUMATROPE

1. Is the request for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **HUMATROPE** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of short stature associated with Turner Syndrome, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of short stature or growth failure in children with SHOX deficiency, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of adult growth hormone deficiency, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist

   If yes, **approve Humatrope 24mg cartridge (GPID 25957) for 12 months by GPID: #4 cartridges per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **HUMATROPE** guideline.

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SOMATROPIN

RENEWAL CRITERIA - HUMATROPE (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Humatrope)** renewal requires a diagnosis of pediatric growth hormone deficiency (GHD), short stature associated with Turner Syndrome, short stature or growth failure in children with SHOX deficiency, growth failure in children born small for gestational age, or adult growth hormone deficiency.

This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

- **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
- **For the diagnosis of short stature associated with Turner Syndrome, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
- **For the diagnosis of short stature or growth failure in children with SHOX deficiency, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for target height following growth hormone therapy
- **For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for target height following growth hormone therapy
- **For the diagnosis of adult growth hormone deficiency, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

NORDITROPIN FLEXPRO

1. Is the request for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **NORDITROPIN FLEXPRO** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of short stature associated with Noonan Syndrome, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of short stature associated with Turner Syndrome, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of short stature born small for gestational age (SGA) in a pediatric patient, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of adult growth hormone deficiency, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
   - **For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - Improvement in body composition

   If yes, **approve Norditropin for 12 months by GPID.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **NORDITROPIN FLEXPRO** guideline.

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SOMATROPIN

RENEWAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Norditropin FlexPro)** renewal requires a diagnosis of Pediatric Growth Hormone Deficiency (GHD), Short Stature Associated with Noonan Syndrome, Short Stature Associated with Turner Syndrome, Short stature born small for gestational age (SGA) in a pediatric patient, Adult Growth hormone Deficiency, or growth failure due to Prader-Willi syndrome.

This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

- **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
- **For the diagnosis of short stature associated with Noonan Syndrome, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
- **For the diagnosis of short stature associated with Turner Syndrome, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
- **For the diagnosis of short stature born small for gestational age (SGA) in a pediatric patient, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
- **For the diagnosis of adult growth hormone deficiency, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
- **For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - Improvement in body composition

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

NUTROPIN AQ, NUTROPIN AQ NUSPIN

1. Is the request for Nutropin AQ or Nutropin AQ NuSpin for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **NUTROPIN AQ and NUTROPIN AQ NUSPIN** guideline.
   If no, continue to #2.

2. Does the patient have one of the following diagnoses and meet the following criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of growth failure secondary to chronic kidney disease (CKD), renewal requires:**
     - The patient has not undergone a renal transplantation
     - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of short stature associated with Turner Syndrome, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of adult growth hormone deficiency, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist

   If yes, **approve for 12 months by GPID.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **NUTROPIN AQ and NUTROPIN AQ NUSPIN** guideline.

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SOMATROPIN

RENEWAL CRITERIA - NUTROPIN AQ, NUTROPIN AQ NUSPIN (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Nutropin AQ, Nutropin AQ NuSpin)**, renewal requires one of the following diagnoses:

- Pediatric Growth Hormone Deficiency (GHD)
- Growth Failure Secondary to Chronic Kidney Disease (CKD)
- Short Stature Associated with Turner Syndrome
- Adult Growth Hormone Deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

- **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient’s predicted adult height
- **For the diagnosis of growth failure secondary to chronic kidney disease (CKD), renewal requires:**
  - The patient has not undergone a renal transplantation
  - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient’s predicted adult height
- **For the diagnosis of short stature associated with Turner Syndrome, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient’s predicted adult height
- **For the diagnosis of adult growth hormone deficiency, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

OMNITROPE

1. Is the request for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **OMNITROPE** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - Improvement in body composition
   - **For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of growth failure associated with Turner Syndrome, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of adult growth hormone deficiency, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist

   If yes, **approve Omnitrope for 12 months by GPID.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **OMNITROPE** guideline.

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SOMATROPIN

RENEWAL CRITERIA - OMNITROPE (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Omnitrope)** renewal requires one of the following diagnoses:

- Pediatric growth hormone deficiency (GHD)
- Growth failure due to Prader-Willi Syndrome (PWS)
- Growth failure in children born small for gestational age (SGA)
- Growth failure associated with Turner Syndrome
- Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

- **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient’s predicted adult height
- **For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:**
  - The mediation is prescribed by or in consultation with an endocrinologist
  - Improvement in body composition
- **For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient’s predicted adult height
- **For the diagnosis of growth failure associated with Turner Syndrome, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient’s predicted adult height
- **For the diagnosis of adult growth hormone deficiency, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

SAIZEN

1. Is the request for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **SAIZEN** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of adult growth hormone deficiency, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist

   If yes, **approve Saizen for 12 months by GPID.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Saizen)** renewal requires a diagnosis of pediatric growth hormone deficiency (GHD) or adult growth hormone deficiency.

   This medication will not be approved for treatment of **ANY** of the following conditions:
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   The following criteria must also be met.
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of adult growth hormone deficiency, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist

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SOMATROPIN

RENEWAL CRITERIA (COTNINUED)

ZOMACTON (formulary called TEV-TROPIN)

1. Is the request for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **ZOMACTON** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   - **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of short stature associated with Turner Syndrome, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of short stature or growth failure in children with SHOX deficiency, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist
     - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
     - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
   - **For the diagnosis of adult growth hormone deficiency, renewal requires:**
     - The medication is prescribed by or in consultation with an endocrinologist

   If yes, **approve Zomacton for 12 months by GPID.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **ZOMACTON** guideline.

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RENEWAL CRITERIA - ZOMACTON (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Zomacton)** renewal requires a diagnosis of pediatric growth hormone deficiency (GHD), short stature associated with Turner Syndrome, short stature in children born small for gestational age (SGA), short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency, or adult growth hormone deficiency.

This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

- **For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height
- **For the diagnosis of short stature associated with Turner Syndrome, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
- **For the diagnosis of short stature or growth failure in children with SHOX deficiency, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
- **For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist
  - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
  - Growth velocity of 2 cm or more compared with what was observed from the previous year and/or patient has not reached 50th percentile for patient's predicted adult height
- **For the diagnosis of adult growth hormone deficiency, renewal requires:**
  - The medication is prescribed by or in consultation with an endocrinologist

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SOMATROPIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Growth Hormones.

FDA APPROVED INDICATIONS

	Ped growth hormone deficiency	Adult growth hormone deficiency	Small for gestational Age	Idiopathic short stature	Turner syndrome	Prader Willi syndrome	HIV-associated wasting	Short bowel syndrome	Noonan syndrome	Short stature homeobox-containing gene	Chronic kidney disease (chronic renal insufficiency)
Zorbtive								✔			
Serostim							✔				
Genotropin	✔	✔	✔	✔	✔	✔					
Norditropin	✔	✔	✔	✔	✔	✔			✔		
Humatrope	✔	✔	✔	✔	✔					✔	
Nutropin	✔	✔		✔	✔						✔
Omnitrope	✔	✔	✔	✔	✔	✔					
Saizen	✔	✔									
Zomacton	✔	✔	✔	✔	✔					✔	

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SOMATROPIN

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COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

TOFACITINIB

Generic	Brand	HICL	GCN	Exception/Other
TOFACITINIB CITRATE	XELJANZ, XELJANZ XR	39768		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial and an inadequate response or intolerance, or contraindication to **at least 3 months** of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months for the requested strength by GPID as follows:**
   - **Xeljanz 5mg: #2 per day.**
   - **Xeljanz XR 11mg: #1 per day.**

   APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #2.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of at least 3 months and an inadequate response or intolerance, or contraindication to at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months for the requested strength by GPID as follows:**
   - **Xeljanz 5mg: #2 per day.**
   - **Xeljanz XR 11mg: #1 per day.**

   APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of at least 6 weeks and an inadequate response or intolerance, or contraindication to at least **ONE** conventional agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - The patient has had an inadequate response or intolerance to a tumor necrosis factor blocker (Humira, preferred) or (Remicade, Renflexis, Inflectra, Avsola, or Simponi, non-preferred) unless there is a medical reason why the patient cannot (contraindication) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months for all strengths by GPID as follows:**
   - **Xeljanz 5mg and 10mg: #2 per day.**
   - **Xeljanz XR 11mg and 22mg: #1 per day.**

   APPROVAL TEXT: Renewal for moderate to severe ulcerative colitis requires that the patient has experienced a positive treatment response.

   If no, continue to #4.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) and meet the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of at least 3 months and an inadequate response or intolerance, or contraindication to at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID for the requested agent as follows:**
   - **Xeljanz 5mg: #2 per day**
   - **Xeljanz oral solution: #10mL per day**

   APPROVAL TEXT: Renewal for polyarticular course juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for approval:

   A. You have **ONE** of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
      4. Polyarticular course juvenile idiopathic arthritis (pcJIA: inflammation of more than 5 joints)

   B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
      1. You are 18 years of age or older
      2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
      3. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   (Initial denial text continued on next page)

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least a 3-month trial of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least **ONE** standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You had an inadequate response (at least 6-week trial) or intolerance to a tumor necrosis factor blocker (Humira, preferred) or (Remicade, Renflexis, Inflectra, Avsola, or Simponi, non-preferred) unless there is a medical reason why you cannot (contraindication)

E. **If you have polyarticular course juvenile idiopathic arthritis (pcJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You have previously tried at least a 3-month trial of ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOFACITINIB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) or psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

     If yes, **approve for 12 months for the requested strength by GPID as follows:**
     - **Xeljanz 5mg: #2 per day.**
     - **Xeljanz XR 11mg: #1 per day.**

     If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) **AND** meet the following criterion?
   - The patient has experienced a positive treatment response

     If yes, **approve for 12 months for all strengths by GPID as follows:**
     - **Xeljanz 5mg and 10mg: #2 per day.**
     - **Xeljanz XR 11mg and 22mg: #1 per day.**

     If no, continue to #3.

3. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

     If yes, **approve for 12 months by GPID for the requested dosage form as follows:**
     - **Xeljanz 5mg: #2 per day**
     - **Xeljanz oral solution: #10mL per day**

     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TOFACITINIB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for renewal:

A. You have **ONE** of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
   4. Polyarticular course juvenile idiopathic arthritis (pcJIA: inflammation of more than 5 joints)

B. **If you have moderate to severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), or polyarticular course juvenile idiopathic arthritis (pcJIA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. If you have moderate to severe ulcerative colitis (UC), renewal also requires:
   1. You have experienced a positive treatment response

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xeljanz/Xeljanz XR.

REFERENCES

- Xeljanz, Xeljanz XR [Prescribing Information]. New York, NY: Pfizer Laboratories Div Pfizer Inc. December 2019.

Created: 10/20
Effective: 11/08/21 Client Approval: 09/27/21 P&T Approval: 06/21

COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

TOPICAL CLINDAMYCIN AGE RESTRICTION GUIDELINE

Generic	Brand	HICL	GPID	Exception/Other
CLINDAMYCIN PHOS/BENZOYL PEROX	ONEXTON 1.2%-3.75% GEL (GRAM) ONEXTON 1.2%-3.75% GEL W/PUMP DUAC 1.2(1) %-5% GEL (GRAM) BENZACLIN 1 %-5 % GEL (GRAM) BENZACLIN 1 %-5 % GEL W/PUMP ACANYA 1.2%-2.5% GEL W/PUMP NEUAC 1.2(1) %-5% GEL (GRAM)		37697 37564 98232 8205 99665 29418	
CLINDAMYCIN PHOS/SKIN CLNSR 19	CLINDACIN PAC 1% KIT		29621	
CLINDAMYCIN/BENZOYL/EMOL CMB94	NEUAC 1.2(1) %-5% CMB CR GEL		36745	
CLINDAMYCIN PHOSPHATE	CLEOCIN T 1% SOLUTION CLEOCIN T 1% MED. SWAB CLEOCIN T 1% LOTION CLEOCIN T 1% GEL (GRAM) CLINDAGEL 1% GEL DAILY EVOCLIN 1% FOAM CLINDACIN ETZ TOPICAL SWAB 1% CLINDACIN P TOPICAL SWAB 1%		31720 45411 31770 45410 20176 23848	
CLINDAMYCIN/TRETINOIN	VELTIN 1.2-0.025% GEL (GRAM) ZIANA 1.2-0.025% GEL (GRAM)		97560	

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COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

TOPICAL CLINDAMYCIN AGE RESTRICTION GUIDELINE

GUIDELINES FOR USE

1. Is the request for an age restriction override?

   If yes, continue to #2. **Note: Non-formulary drugs should still be evaluated for formulary exception when applicable.**
   If no, this guideline does not apply.

2. Does the patient have one of the following diagnoses?
   - Hidradenitis suppurativa
   - Follicular disorder
   - Rosacea

   If yes, **approve for 12 months by HICL within any applicable formulary quantity limits.**
   If no, continue to #3.

3. Does the patient have the diagnoses of acne?

   If yes, continue to #4.
   If no, continue to #7.

4. Is the requested medication prescribed by a Dermatologist?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for a combination product that contains benzoyl peroxide?

   If yes, **approve for 12 months by HICL with any applicable formulary quantity limits.**
   If no, continue to #6.

6. Will the medication be used with benzoyl peroxide?

   If yes, **approve for 12 months by HICL with any applicable formulary quantity limits.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TOPICAL CLINDAMYCIN AGE RESTRICTION GUIDELINE

GUIDELINES FOR USE (CONTINUED)

7. Does the patient meet one of the following?
   - Diagnosis is an FDA approved indication
   - A medically accepted indication and it is considered safe and effective by approved compendia (medical references), peer-reviewed medical literature, or accepted standards of medical practice.

   If yes, **approve for 12 months by HICL within any applicable formulary quantity limits.**
   If not, do not approve.
   DENIAL TEXT: The guideline named **CLINDAMYCIN PHOSPHATE TOPICAL** requires that the patient has one of the following diagnoses: Acne, Hidradenitis suppurativa, Follicular disorder, Rosacea, an FDA approved indication or a medically accepted indication that is considered safe and effective by approved compendia (medical references), peer-reviewed medical literature, or accepted standards of medical practice.

   When used for the treatment of acne, the following requirements must also be met:
   1. The medication must be prescribed by a dermatologist
   2. The medication must be used in combination with benzoyl peroxide (unless it is already included in the requested combination product)

Created: 01/22
Effective: 01/24/22 Client Approval: 01/03/22 P&T Approval: N/A

COOK COUNTY HEALTHCARE AND HOSPITALS SYSTEMS
PRIOR AUTHORIZATION GUIDELINES

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