RX.PA.033.CCH SPECIALTY DRUG MANAGEMENT

The purpose of this policy is to define the prior authorization process for **specialty drugs processed under the medical benefit that do not have an existing drug specific policy.**

A specialty drug is any high-cost drug including injectables, infused products, oral agents, or inhaled medications, which require unique storage/ shipment and additional education and support from a health care professional. Specialty drugs offer treatment for serious, chronic, life-threatening diseases and are covered under medical benefits.

DEFINITIONS

Applicable Drugs (*Not All-Inclusive*)

J-Code	Brand	Generic	Route of Administration	Notes
J1931	Aldurazyme	Injection, laronidase, 0.1mg	IV	
J0584	Crysvita	INJECTION BUROSUMAB-TWZA 1 MG	Subcutaneous	
J7351	Durysta	bimatoprost implant	IV	
J1743	Elaprase	Injection, idursulfase, 1mg	IV	
J1458	Naglazyme	Injection, galsulfase, 1mg	IV	
A9607	Pluvicto	Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie	IV	Radio-pharmaceutical
J1300	Soliris	Injection, eculizumab	IV	
J3241	Tepezza	teprotumumab-trbw	IV	
J1823	Uplizna	INJECTION INEBILIZUMAB-CDON 1 MG	IV	
J1427	Viltepso	INJECTION VILTOLARSEN 10 MG	IV	
J1322	Vimizim	Injection, elosulfase alfa, 1mg	IV	
TBD	Nulibry	Injection, fosdenopterin	IV	

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.
The specialty drugs listed in this policy are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed for an FDA-approved or compendia supported indication*
- *FDA-Approved Indications ONLY:* Must be used consistently with manufacturer's prescribing information (e.g., contraindications, limitations, etc.)
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Member must meet one of the following:
    - Be included within the patient population identified in the indication OR
    - Meet the eligibility criteria for the clinical studies

***NOTE:** For indications/diagnoses that are not FDA-approved, or compendia supported, PA.252.CCH Determination of Medical Necessity will be utilized.

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

REFERENCES

N/A

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial Review	3/22
Updated authorization durations to 1 year	2/23
Added several applicable drugs to drug table	XX/XX

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure

Disclaimer

CountyCare medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of CountyCare and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

CountyCare reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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