RX.PA.033.MPC Specialty Drug Management

PURPOSE

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 (e.g., higher than $830/month per Medicare Part D) 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 is covered under pharmacy or medical benefits.

The specialty drugs listed in this policy are subject to the prior authorization process.

PROCEDURE

A. Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed for an FDA approved or compendia supported indication
- Must be used consistently with manufacturer's prescribing information (i.e. 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 stud(ies)
- Must be prescribed by or in consultation with a provider who specializes in the treatment of the indication
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling or within compendia supported guidelines
- Must have a documented trial and failure or intolerance/contraindication to FDA approved or compendia supported first line agents for requested medications utilized as second line therapies/alternative agents
    - Trial and failure of treatment(s) defined in policy RX-PA-101: Treatment Optimization.

B. Specialty drugs will be considered investigational or experimental for any other use and coverage may be provided if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia (AHFS-DI, DrugDex, Lexi-Drug, etc.) or at least two published peer-reviewed randomized controlled trials for the treatment of the

diagnosis(es) for which it is prescribed. Abstracts (including meeting abstracts) are excluded from review consideration. These requests will be reviewed on a case-by-case basis to determine medical necessity.

C. 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:

MPC Renewal:

- Chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.
- Must be prescribed by or in consultation with a provider who specializes in the treatment of the indication

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria)
- Provider has a documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year

Codes:

APPLICABLE CODES:	
CODE	**DESCRIPTION**
C9293	Injection, glucarpidase, 10 units
J0480	Injection, basiliximab, 20 mg
J0567	Injection, cerliponase alfa, 1 mg
J0850	Injection, cytomegalovirus immune globulin intravenous (human), per vial
J1301	Injection, edaravone, 1 mg
J1324	Injection, enfuvirtide, 1 mg
J1640	Injection, hemin, 1 mg
J1746	Injection, ibalizumab-uiyk, 10 mg
J1930	Injection, lanreotide, 1 mg

J2278	Injection, ziconotide, 1 mcg
J2783	Injection, rasburicase, 0.5 mg
J2791	Injection, Rho D immune globulin (human), (Rhophylac), intramuscular or intravenous, 100 IU
J7178	Injection, human fibrinogen concentrate, not otherwise specified, 1 mg
J7511	Lymphocyte immune globulin, antithymocyte globulin, rabbit, parenteral, 25 mg
J7516	Cyclosporine, parenteral, 250 mg
J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg
J7189	Factor Viia (antihemophilic factor, recombinant), (novoseven rt), 1 microgram
J7195	Injection, factor IX (antihemophilic factor, recombinant) per IU, not otherwise specified
J7205	Injection, factor VIII fc fusion protein (recombinant), per IU
J7185	Injection, factor VIII (antihemophilic factor, recombinant) (xyntha), per I.U.

REFERENCES

N/A

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Addition of trial of first line agents for medications utilized as second line therapies	*08/2025*
Addition of provider specialty as a requirement for initial and reauthorization criteria	*04/2025*
Annual Review	*02/2025*
Annual Review *Change in Non-MPC renewal to renewal from previous insurer*	*02/2024*
Selected Revision *Addition of Applicable Codes: J7189, J7195, J7205, J7185*	*01/2024*

Selected Revision *Removal of Applicable Codes: J0775, J3489, J7316, Q0138, Q0139* *Addition of J2353, Injection, octreotide, depot form for intramuscular injection, 1 mg*	*07/2023*
Annual review	*02/2023*
Selected Revision *Addition of MPC vs Non-MPC Renewal Criteria*	*07/2022*
Additional of off-label restrictions	*05/2022*
Annual review	*02/2022*
P&T Review	*11/2020*