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 $670/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)

B. Specialty drugs listed in this policy 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 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 3 months
Reauthorization	Up to 1 year

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.

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
J3489	Injection, zoledronic acid, 1 mg
J7178	Injection, human fibrinogen concentrate, not otherwise specified, 1 mg
J7316	Injection, ocriplasmin, 0.125 mg
J7511	Lymphocyte immune globulin, antithymocyte globulin, rabbit, parenteral, 25 mg
J7516	Cyclosporine, parenteral, 250 mg

Q0138	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-ESRD use)
Q0139	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for ESRD on dialysis)

REFERENCES

N/A

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Addition of off-label restrictions	*05/2022*
Annual review	*02/2022*
Removal of J0775 from policy. Medication is reviewed under policy #097	*01/2022*
P&T Review	*11/2020*