BlueCross BlueShield of North Carolina

Medicare Part C Medical Coverage Policy

Immunosuppressant Medications

Origination: June 17, 2009
Review Date: March 15, 2023
Next Review: March, 2025

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION

Immunosuppressant medications are given to a transplant recipient to decrease the activity of the immune system and prevent the member's immune system from attacking the transplanted organ.

POLICY STATEMENT

Coverage will be provided for immunosuppressants when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions for will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCD);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE:

PART B COVERAGE CRITERIA:

A. Preauthorization by the Plan may be required;
B. Immunosuppressive therapy medications are covered when all of the following criteria are met: (1-5)

1. Immunosuppressive drugs are prescribed following either:
    a. Kidney, heart, liver, bone marrow, stem cell, lung or heart/lung transplant; **or**

    b. Whole organ pancreas transplant performed concurrent with or subsequent to a kidney transplant for a diagnosis of diabetic nephropathy (performed on or after July1, 1999); **or**

    c. Intestinal transplant (performed on or after April 1, 2001); **or**

    d. Pancreatic islet cell transplant or pancreatic tissue transplantation performed on or after October 1, 2004, that is conducted as part of a National Institutes of Health (NIH)-sponsored clinical trial; **or**

    e. Pancreas transplants alone (performed on or after April 26, 2006) that meet the following criteria:
        (i) The transplant is performed at a facility that is Medicare-approved for kidney transplantation; **and**

        (ii) Member must have a diagnosis of Type I Diabetes **and**:
            a. Beta cell autoantibody positive; **or**

            b. Demonstrate insulinopenia. A fasting glucose must be obtained when performing a fasting C-peptide determination. Fasting C-peptide levels are considered valid when a concurrently obtained fasting glucose is less than 225mg/dL; **and**

(iii) Have a history of labile insulin-dependent diabetes mellitus resulting in documented recurrent, severe, acutely life-threatening metabolic complications requiring hospitalization(s). Complications may include frequent hypoglycemia where the patient is unaware, recurring severe ketoacidosis, or recurring severe hypoglycemic attacks; **and**

(iv) Under the care of an endocrinologist and have clinical documentation denoting optimal and intensive management was provided for at least twelve (12) months, having received the most medically-recognized advanced insulin formulations and delivery systems; **and**

(v) Demonstrate being able to emotionally and mentally understand the significant risks associated with surgery and be able to effectively manage the lifelong need for immunosuppression; **and**

(vi) Be a suitable candidate for transplantation; **and**

2. The transplant met Original Medicare coverage criteria in effect at the time (e.g., approved facility for kidney, heart, intestinal, liver, lung, or heart/lung transplant; national and/or local medical necessity criteria; etc.); **and**

3. The member was enrolled in Medicare Part A at the time of the transplant; **and**

4. The member was enrolled in Medicare Part B at the time the drugs are dispensed; **and**

5. Drugs are allowed to be furnished by multiple delivery methods based on the series of dates below:
    i. For DOS on or after August 1, 2016 through April 2, 2019, mail-order deliveries may be mailed one (1) or two (2) days prior to a member's discharge from an inpatient facility to a qualified place of service (such as home or custodial care facility). The DOS on the claim must be the date of discharge.
    ii. For DOS on or after April 3, 2019 mail-order deliveries may be mailed one (1) or two (2) days prior to a member's anticipated date of discharge from an inpatient facility to a qualified place of service or alternate address, such as the inpatient hospital that performed the transplant or alternative location where the member is temporarily staying (such as temporary housing). The DOS on the claim must be the date of discharge.

Immunosuppressive medications are covered under the Part D, prescription drug benefit, if the transplant was covered under a commercial insurance plan.

Immunosuppressive drug coverage is limited to thirty-six (36) months under the Part B benefit, for members whose Medicare entitlement is based solely on end-stage renal disease (ESRD). After the thirty-six (36) months, the medication may be covered under the Part D, prescription drug benefit.

WHEN COVERAGE WILL NOT BE APPROVED UNDER PART B BENEFIT
If the above criteria are not met, the medication request will be denied as non-covered.

A. Immunosuppressive drugs will be denied under Part B as non-covered when used for the treatment of members with non-transplant related diagnosis (e.g. rheumatoid arthritis, connective tissue diseases, and vasculitis). Drugs may be covered under Part D if applicable.

B. Immunosuppressive drugs used following partial pancreatic tissue transplantation or islet cell transplantation performed outside the context of a clinical trial or performed before October 1, 2004, will continue to be non-covered under the Part B or Part D benefit.

PART D COVERAGE CRITERIA:

A. Preauthorization by the Plan is required;

1. If the above criteria are not met for coverage under the Part B benefit, the medication may be covered under Part D if:
    a. The medication is administered for an FDA approved use;
    b. The medication is on a prescription from a physician;
    c. The medication is used and sold in the United States
    d. The medication is used for a medically accepted indication.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable Codes: *J2920, J2930, J0485, J7500, J7501, J7502, J7503, J7504, J7505, J7507, J7508, J7509, J7510, J7511, J7512, J7513, J7515, J7516, J7517, J7518, J7520, J7525, J7527, J7599, J8530, J8610, Q0510, Q0511, Q0512*

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES

Immunosuppressive drugs will be covered for islet cell transplants conducted as part of an NIH-sponsored clinical trial, Original Medicare, instead of Blue Medicare, will pay for the routine costs, as well as transplantation and appropriate related items and services. The term “routine costs” means reasonable and necessary routine patient care costs, including immunosuppressive drugs and other follow-up care. In addition, Original Medicare will cover transplantation of pancreatic islet cells.

Coverage of parenteral azathioprine or methylprednisolone is limited to those situations in which the medication cannot be tolerated or absorbed if taken orally and is self-administered by the member.

GLOSSARY OF TERMS

Insulinopenia: Fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory’s measurement method.

Labile: Brittle or medically-uncontrollable diabetes

References:

1. Medicare Local Coverage Determination for Immunosuppressive Drugs – CGS Administrators (L33824); Effective date: 10/01/2015, Accessed via www.cms.gov 2/20/2023.
2. Medicare Local Coverage Article for Immunosuppressive Drugs (A52474); Effective date: 10/01/2015; Accessed via www.cms.gov/ 2/20/2023.
3. Medicare Prescription Drug Benefit Manual,(Revision 18, 1/15/16)- Chapter 6, Part D Drugs and Formulary Requirements, Section 10.2, reviewed online at www.cms.gov on 2/20/2023.

Policy Implementation/Update Information:

Revision Date: New policy June 2009
Revision Date: 4/28/11: Minor language added per LCD L11521 to Indications For Coverage section, added language from Limitations section. Minor language added per LCD L11521; added items #1 and #3 from Special Notes to When Coverage Will Not Be Approved section. Moved language from Limitations section to Indications for Coverage and removed this section.
Revised Date: 08/12/2013; annual review, updated codes J7527, J8610 and J0485.
Revision Date: 09/18/2015: Annual review; minor edits for policy consistency; added second paragraph to Special Notes per CMS guidance. October 29, 2015 updated LCD due to ICD-10 update only. December 16, 2015 coding update only.
Revision Date: 09/20/17 No CMS Updates, Minor Revisions Only.
Revision Date: 3/8/19 CMS Update; LCA updated for Delivery Requirements of Medications: Added to Indications For Coverage: B. 5. Drugs are allowed to be furnished in multiple delivery methods based on the series of dates below: For DOS prior to August 1, 2016 the drugs are furnished on or after the date of discharge from the hospital following a covered organ transplant. For DOS on or after August 1, 2016 through April 2, 2019, mail-order deliveries may be mailed one (1) or two (2) days prior to a member’s discharge from an inpatient facility to a qualified place of service (such as home or custodial facility). The DOS on the claim must be the date of discharge. For DOS on or after April 3, 2019 mail-order deliveries may be mailed one (1) or two (2) days prior to a member’s anticipated date of discharge from an inpatient facility to a qualified place of service or alternate address, such as the inpatient hospital that performed the transplant or alternative location where the member is temporarily staying (such as temporary housing). The DOS on the claim must be the date of discharge.
Revision Date: 3/17/21; Annual Review; No CMS Updates. Minor Revisions Only.
Revision Date: March 15, 2023; Annual Review; No CMS Updates. Minor Revisions only.

Approval Dates:

Medical Coverage Policy Committee: March 15, 2023

Policy Owner: Beth Sell, RN, BSN
Medical Policy Coordinator