Provider Compliance Tips for Immunosuppressive Drugs

What’s Changed?

• Updated the improper payment rate for immunosuppressive drugs for the 2020 reporting period

You’ll find substantive content updates in dark red font.

Provider Types Affected

Physicians and Non-Physician Practitioners (NPPs) who write prescriptions for immunosuppressive drugs

Introduction

This publication educates providers on how to prevent denials for prescription drugs used in immunosuppressive therapy. You’ll find coverage requirements and billing resources to help you find the correct elements and documentation to send with claims that bill for these drugs. This document will help you recognize correct billing practices for immunosuppressive drugs.
Background

The 2020 reporting period, the Medicare Fee-for-Service (FFS) improper payment rate for immunosuppressive drugs is 17%, representing a projected improper payment amount of $60.8 million.

Reasons for Denial

For the 2020 reporting period, insufficient documentation accounted for 63.6% of improper payments for immunosuppressive drugs.

Other types of errors for immunosuppressive drugs:

- Incorrect coding (1.3%)
- Medical necessity (0.2%)
- Other (28.1%)

How to Prevent Denials

Medicare covers prescription drugs used in immunosuppressive therapy under the Durable Medical Equipment, Prosthetics, Orthotics and Supplies Program (DMEPOS) benefit if they meet all the following criteria:

- Health care providers prescribe Immunosuppressive drugs following transplants for:
  - Kidney, heart, liver, bone marrow and stem cell, lung, or heart and lung transplant
  - Whole organ pancreas transplant performed concurrent with or subsequent to a kidney transplant because of diabetic nephropathy (performed on or after July 1, 1999)
  - Intestinal transplant (performed on or after April 1, 2001)
  - Pancreatic islet cell transplant or partial pancreatic tissue transplantation performed on or after October 1, 2004 conducted as part of a National Institutes of Health (NIH)-sponsored clinical trial
  - Pancreas transplants alone (performed on or after April 26, 2006) that meet the 6 criteria listed in Local Coverage Article: Immunosuppressive Drugs-Policy Article (A52474)
- The transplant met Medicare coverage criteria in effect at the time (for example, approved facility for kidney, heart, intestinal, liver, lung, or heart and lung transplant; national or local medical necessity criteria, or both)
- The patient has Medicare Part A at the time of the transplant
- The patient has Medicare Part B at the time a health care provider dispenses the drugs
- The health care provider delivers the drugs according to the requirements outlined in Local Coverage Article: Immunosuppressive Drugs-Policy Article (A52474)
Consider the following factors when submitting immunosuppressive drug claims to Medicare:

- Immunosuppressive drugs require dosage, frequency, and route of administration. They must conform to generally accepted medical practice and meet medical necessity requirements to prevent or treat the rejection of an organ transplant.
- Medicare limits the quantity of immunosuppressive drugs dispensed to a 30-day supply.
- Refill requirements
  - Contact to the patient about the refills must take place no sooner that 14 days before delivery or shipping date.
  - For delivery of refills, the supplier must deliver the DMEPOS product no sooner that 10 calendar days before the end of usage for the current product.

Include the following elements with submitted documentation to meet Medicare FFS coverage requirements for Immunosuppressive drug claims:

- Standard Written Order (SWO)
- Medical Record Information (including continued need and use if applicable)
- Correct Coding
- Proof of Delivery

**Resources**

- [2020 Medicare Fee-For-Service Supplemental Improper Payment Data](#)
- [Local Coverage Determination (LCD): Immunosuppressive Drugs (L33824)](#)
- [Local Coverage Article: Immunosuppressive Drugs - Policy Article (A52474)](#)
- [Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME Medicare Administrative Contractors (A55426)](#)
- [Standard Elements for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Orders Prior to Delivery and, or Prior Authorization Requirements (SE20007)](#)

**Contact your MAC** for any updates or changes to the Policy Article (PA) and the LCD regarding policy and general documentation requirements.

**Medicare Learning Network® Content Disclaimer, Product Disclaimer, and Department of Health & Human Services Disclosure**

The Medicare Learning Network®, MLN Connects®, and MLN Matters® are registered trademarks of the U.S. Department of Health & Human Services (HHS).