



## **CENTER FOR MEDICARE**

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**DATE:** April 1, 2019  
**TO:** All Part D Sponsors  
**FROM:** Amy Larrick Chavez-Valdez  
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**SUBJECT: Using CMS Data when making B vs D Coverage Determinations for Immunosuppressants used to Prevent Transplant Rejections**

The Centers for Medicare & Medicaid Services (CMS) announced in the 2019 Call Letter a new process for Part D sponsors to follow when determining appropriate coverage for immunosuppressants used to prevent transplant rejections. Part D sponsors are responsible for determining whether these immunosuppressants are coverable under Part D because immunosuppressants used for Medicare-covered transplants are covered under Part B. We are issuing this guidance in response to questions we have received concerning the new process since its implementation on January 1, 2019.

### **Using CMS Data**

As noted in the Call Letter, a Medicare Advantage plan that has medical claims history of a Medicare-covered transplant for an enrollee must first utilize its own transplant claims data when determining which benefit covers immunosuppressants for transplant rejection. However, in the absence of such plan data, all Part D sponsors are expected to use data provided by CMS when determining whether a transplant was covered by Medicare, and to make appropriate coverage decisions for the subsequent immunosuppressant drugs based on that information. Specifically, sponsors are expected to use CMS data provided by the Medicare Advantage Prescription Drug (MARx) system, the Additional Beneficiary Information Initiatives (ABII) portal, and CMS program audits.

The MARx system provides Part D plans information for Medicare coverage of renal (kidney) transplants. MARx uses daily Transactions Reply Reporting (TRR) data that is intended to convey to Part D plans the presence of a renal transplant, and a user interface function to present Medicare entitlement data. The ABII portal allows Part D sponsors to access Medicare claims data for Medicare-covered non-renal transplants (e.g. heart, liver, lung, pancreas) when immunosuppressant therapy is expected afterwards.

Part D sponsors may receive a TRR specifying a renal transplant date which does not fall within the Medicare entitlement periods presented within MARx. This has led to plan confusion as to

whether the renal transplant was covered by Medicare. When this occurs, we are clarifying that Part D plans are expected to cover the immunosuppressant drug(s) under Part D. Therefore, it is critical that Part D sponsors always utilize both the transplant date and Medicare entitlement data provided via MARx when making these B vs D determinations.

### **Timing Considerations**

Some Part D sponsors have asked for clarification about the acceptable lag time between when a plan receives CMS notification of a Medicare-covered transplant and when they must apply that information to future immunosuppressant claims. The 2019 Call Letter makes it clear that Part D sponsors are expected to rely on CMS data as soon as the information is made available to them. For example, if a plan has been paying for immunosuppressants used for transplant rejections under Part D because there was no information about a Medicare-covered transplant provided via MARx, ABII or a CMS Audit, and MARx is then updated with information specifying that the transplant was covered by Medicare (i.e. MARx now shows transplant date within Medicare entitlement period), we expect that the Part D plan will implement new edits effective the date the new information was received to prevent future Part D claims from processing. We also want to make it clear that while the plan must notify affected enrollees that Part D can no longer cover their immunosuppressants, such notification can follow implementation of new point-of-sale (POS) edits and must not delay the Part D plan's acting upon newly-received data indicating the transplant was covered by Medicare.

CMS encourages plans to implement B vs D POS edits only when they have received information from CMS (i.e. via MARx, ABII or Audit) indicating that the enrollee had a Medicare-covered transplant. This eliminates the need for enrollees to request coverage determinations when the plan does not have any CMS data indicating that the enrollee received a Medicare-covered transplant. Nevertheless, regardless of whether a plan only implements POS edits when it has received information from CMS that the enrollee has had a Medicare-covered transplant or not, the plan must be prepared to adjudicate coverage determination requests timely following any POS claim rejections. CMS expects that such coverage determination requests would meet the medical exigency standard as defined in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance<sup>1</sup>.

### **Coverage of Immunosuppressants Prescribed for Non-transplant Related Purposes**

Some immunosuppressant drugs used to prevent transplant rejections also can be prescribed for purposes other than transplant rejection, including in people who have previously had a transplant. In these situations, Part B would not cover the immunosuppressants being used for non-transplant purposes, and therefore, Part D coverage may be appropriate depending upon the circumstances.

Part D sponsors should take these clarifications into account immediately and are encouraged to access the additional FAQs within the ABII portal. Additional questions can be submitted to [PartD\\_COB@cms.hhs.gov](mailto:PartD_COB@cms.hhs.gov).

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<sup>1</sup> Section 10.4.1