

Policy & Procedure

Policy Title: Formulary Transition		
LOB: Medicare	Section: MA-PD	Effective Date: June 2018

I. PURPOSE

The Formulary Transition Process determines the manner for assisting Members prescribed Part D drugs that are not covered by Integra's Part D formulary. It allows for medical review of such Non-formulary Drug requests, and in the event such a request is found not medically necessary, the policy determines the manner in which Members are switched to therapeutically appropriate formulary alternatives.

II. CRITERIA/STANDARD

Integra's transition process is consistent with CMS rules and guidance, and its implementation is contingent upon CMS approval.

III. POLICY OVERVIEW

a. TARGET GROUPS

It's possible for Integra Members in the following groups to receive drug therapy that is not included on the Integra Part D formulary:

- i. New Members entering the Plan at the start of a contract year and/or following the annual coordinated election period;
- ii. Newly eligible Medicare Beneficiaries transitioning from other coverage;
- iii. Members transitioning from one plan to another after the start of a contract year;
- iv. Current Members affected by negative formulary changes across contract years, and

- v. Members residing in long-term care (LTC) facilities, including those admitted to or discharged from an LTC facility.

b. PHARMACEUTICAL SCOPE

This transition policy applies to Non-formulary Drugs, including:

- i. Part D drugs that are not on the Integra Part D formulary;
- ii. Part D drugs previously approved for coverage under an exception once the exception expires, and
- iii. Part D drugs that are on the Integra Part D formulary, but require prior authorization, step therapy, or approved quantity limits lower than the member's current dose under Integra's utilization management rules.

c. FORMULARY TRANSITION DELEGATION

Integra delegates formulary management to a contracted PBM (EnvisionRx) whose P&T committee reviews procedures for coverage determination and exceptions. The committee also determines the process for switching new Members to therapeutically appropriate formulary alternatives if an affirmative medical necessity determination is not made. Integra monitors EnvisionRx and the transition process as a whole to ensure the following criteria are met:

- i. Integra ensures EnvisionRx has systems capable of providing a temporary supply of non-formulary Part D drugs in order to accommodate the needs of a Member. This supply is sufficient to allow Integra and the Member enough time to work with the prescriber to resolve the issue, either through an appropriate switch to a therapeutically equivalent medication or by completing an exception request for maintaining coverage of the drug in question for reasons of medical necessity.
- ii. Integra ensures that the PBM Transition Fill (TF) processing and coding applies point-of-sale (POS) messaging to pharmacies, providing for at least a one-time, temporary 30-day fill. Additionally, Integra ensures the TF allows multiple fills up to a cumulative 30-day supply in order to accommodate fills for amounts less than prescribed. Members may utilize these TF components any time during the first 90 days of their enrollment in the plan.
- iii. Integra ensures that the cost sharing tier for a temporary supply of drugs provided under the transition process will not exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible Members.
- iv. For non-LIS eligible Members, Integra ensures that:
 - The non-formulary Part D drugs transition supply receives the same cost sharing that would apply for non-formulary drugs approved through a formulary exception in accordance with §423.578(b), and

- The formulary transition supply receives the same cost sharing for a formulary drug, subject to utilization management edits provided during the transition that would apply if the utilization management criteria were met.
- v. Integra ensures that in the long-term care setting:
- The transition policy will provide for at least a 30-day fill that is consistent with the applicable dispensing increment in the long-term care setting (unless the member presents with a prescription written for less), with refills provided if needed during the first 90 days of a member's enrollment in a plan;
 - After the transition period has expired, the transition policy will provide for at least a 31-day emergency supply of non-formulary Part D drugs (unless the member presents with a prescription written for less than the 31 days) while an exception or prior authorization determination is pending, and
 - For Members being admitted to or discharged from a LTC facility, early refill edits will not be used to limit appropriate and necessary access to their Part D benefit, and such Members will be allowed to access a refill upon admission or discharge.
- vi. Integra will only apply the following utilization management edits during transition at point of sale (POS):
- Edits to determine Part A or B versus Part D coverage,
 - Edits to prevent coverage of non-Part D drugs, and
 - Edits to promote safe utilization of a Part D drug.

Step therapy and prior authorization edits will be coded to be resolved at POS.

- vii. Integra will allow refills for transition prescriptions dispensed for less than the written amount due to quantity limit safety edits or drug utilization edits that are based on approved product labeling.
- viii. Integra will apply its transition processes to a brand-new prescription for a Non-formulary Drug if a distinction cannot be made between a brand-new prescription for a Non-formulary Drug and an ongoing prescription for a Non-formulary Drug at POS.
- ix. Integra uses EnvisionRx to fulfill transition notices. Envision sends written notice via U.S first class mail to Member within three business days of adjudication of a temporary transition fill. The notice includes:
- An explanation of the temporary nature of the transition supply the Member has received;

- Instructions for working with Integra and the Member's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the Integra Part D formulary;
- An explanation of the Member's right to request a formulary exception, and
- A description of the procedures for requesting a formulary exception.

For long-term care residents dispensed multiple supplies of a Part D drug in increments of 14 days or less, the written notice will be provided within three business days after adjudication of the first temporary fill.

- x. EnvisionRx uses the Transition Notice provided by Integra. Integra will obtain CMS approval for the notice using the CMS model Transition Notice via the file-and-use process if required, or by submitting a non-model Transition Notice to CMS for marketing review (subject to a 45-day review). EnvisionRx will use reasonable efforts to provide notice of TF to prescribers to facilitate transitioning of Members.
- xi. Integra ensures that prior authorization or exception request forms are made available upon request to both Members and prescribing physicians via mail, fax, or email. These forms are also available on Integra's web site.
- xii. Integra extends its transition policy across the Contract Year should a Member enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply.
- xiii. Integra makes general transition process information available to Members via the Medicare Prescription Drug Plan Finder link to its web site, as well as in pre and post-enrollment materials.
- xiv. Integra provides a process for Members to receive necessary Part D drugs via an extension of the transition period - on a case-by-case basis - to the extent that their exception requests or appeals have not been processed by the end of the minimum transition period, and until such time as a transition has been made (either through a switch to an appropriate formulary drug or a decision on an exception request).
- xv. Integra will implement the transition process for renewing Members whose drugs will be affected by negative formulary changes in the upcoming Contract Year. Integra will offer its transition processes for encouraging a transition prior to the beginning of the Contract Year.
- xvi. Integra will ensure that EnvisionRx will maintain the ability to support routine and CMS-required reporting, as well as the ability to respond to ad hoc requests for:
 - Denied claim reports and
 - Paid TF claim reports for new and renewing Members.

It will also maintain the ability to support test TF claim processing in response to ad hoc requests and will regularly review and audit TF program data and system operations to monitor adherence with Part D Transition Fill requirements.