CY 2019 Step Therapy Qs & As
August 29, 2018

1. **Question:** May MA plans choose to implement voluntary step therapy programs as opposed to making the program mandatory for enrollees?

   Response: Yes, MA plans may implement both voluntary and mandatory step therapy programs as long as all guidelines are followed.

2. **Question:** Can CMS clarify how rewards to incentivize enrollee participation in a drug management care coordination program should be structured?

   Response: MA plans have flexibility in how they calculate and administer rewards for participation in the drug management care coordination program as long as they follow the requirements at 42 CFR 422.134. Per CMS regulations and guidance, rewards must be earned by completing an entire service or activity (or combination of services/activities), as established by the MA plan, and may not be offered for completion of less than any/all required component(s) of the eligible service or activity. This means that an enrollee may not receive a reward until after they have participated in the program; however, plans are expected to reasonably define the scope of the "entire service or activity" within their RI Program design and assign a value of the reward or incentive accordingly. For example, a plan may decide to offer one larger reward for participation in the whole program or the plan may decide to give smaller rewards for completing individual elements within the program (e.g., medication review, reviewing educational material, etc.).

   Consistent with 42 CFR §422.134, plan rewards cannot be offered in the form of cash or monetary rebate, including lowered cost-sharing, but may be offered as gift cards or other items of value to all eligible enrollees. Plans have discretion on how to calculate and distribute rewards as long as each reward is valued at an equivalent to more than half the amount saved on average per participant by a more efficient use of health care resources, promotion of improved health, or prevention of injuries and illness. CMS believes this is consistent with the requirement that rewards and incentives be of a value that may be expected to affect enrollees' behavior without exceeding the value the health related service or activity, in this case the drug management care coordination program or distinct elements of it. Note that plans are expected to report the value of the offered reward(s) on per member basis in comparison to the average planned per participant savings in the annual Part C Reporting Requirements.

3. **Question:** Can CMS provide more information on the drug management care coordination program?

   Response: At a minimum, all enrollees who are subject to a Part B step therapy limit must be offered participation in a drug management care coordination program that meets the standards outlined in the August 7, 2018 HPMS memo. The program should at least consist of an interactive medication review and associated consultations for enrollees to discuss all current medications and perform medication reconciliation and follow-up

when necessary; educational materials and information for enrollees about drugs within the drug management care coordination program; and medication adherence strategies to help enrollees with their medication regimen.

It is the enrollee's choice whether to participate in the program or not. The requirement that enrollees who are subject to Part B step therapy must be offered the program is a minimum requirement. MA plans may expand the program offering to all enrollees.

4. **Question:** How does CMS interpret the requirement that step therapy only be applied to new prescriptions or administrations of Part B drugs for enrollees that are not actively receiving the affected medication?

   Response: Medicare Advantage Organizations may only apply step therapy policies to new prescriptions or new administrations of Part B drugs. This means that enrollees currently receiving a particular drug under Part B cannot be required under a step therapy policy to change their medication. For example, a new plan enrollee currently undergoing a particular drug therapy cannot be forced to switch to the preferred drug therapy of the plan upon enrollment. Similarly, an existing enrollee already undergoing a particular drug therapy must not be required to change therapies should a plan establish or update a step therapy program. Consistent with Part D rules, CMS expects plans will follow a look-back period of at least 108 days to determine whether the enrollee is eligible for a new start prescription.

5. **Question:** Can CMS provide additional guidance on the language that should be included in the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents and explicitly state where the language should be inserted?

   Response: MA plans must, at a minimum, disclose that Part B drugs may be subject to step therapy requirements in the plan's ANOC and EOC documents. The ANOC and EOC can list each Part B drug that will be subject to step therapy or it can be more general.

   In the ANOC, this information must be included under the Changes to Benefits and Costs for Medical Services. In the EOC, this information must be included in the Medical Benefits Chart under "Medicare Part B prescription drugs." If these documents are already in production, plans may send out an addendum to the ANOC and EOC to appropriately inform enrollees of the change. ANOCs are due by 9/30 and EOCs are due by 10/15, so those deadlines remain for the addendum.

   Note that Plan Finder links to plan websites, on which the ANOC and EOC documents that address utilization management procedures, such as step therapy can be found.

6. **Question:** Are plans required to submit their step therapy requirements to CMS?

   Response: No. At this time, Medicare Advantage Organizations are not required to submit step therapy criteria for affected Part B Drugs to CMS. However, CMS notes that it is critical that MA plans continue to comply with the statutory requirement that they provide access to all Part A and Part B benefits that would be available in Original Medicare. Step therapy or other utilization management policies may not be used as an unreasonable means to deny coverage of medically necessary services or to eliminate access to a Part B covered benefit.

7. **Question**: Are plans required to review all National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) at all times? Can plan criteria be stricter than anything within an NCD or LCD?

   Response: Organizations have been and remain subject to the applicable MA regulations to comply with national and in some cases, local coverage determinations. Step therapy protocols cannot be stricter than an NCD or LCD with specified step therapy requirements.

8. **Question:** Can MA plans apply step therapy for other Part B products like test strips, meters, or other Part B medical devices, which are generally dispensed by a pharmacy?

   Response: The Part B step therapy guidance governs Part B drugs. However, MA plans continue to have the ability to use utilization management tools, such as prior authorization for other Part B covered items, such as durable medical equipment (DME), to ensure enrollees are receiving medically appropriate health care services in a cost effective manner. We also note that MA plans may specify brands and manufacturers as preferred and charge lower cost-sharing for the preferred brands or may limit DME to only those preferred brands and manufacturers, as described in the MA regulations at 42 CFR § 422.100(l)) and Chapter 4 section 10.12.2 of the Medicare Managed Care Manual.

9. **Question:** Can MA plans require an off-label use of one Part B drug before a different Part B drug?

   Response: Consistent with existing Part D guidelines, MAOs will be permitted to require an enrollee to try and fail drugs supported only by an off-label indication (an indication only supported in the statutory compendia) before providing access to a drug supported by an FDA approved indication (on-label indication) if the off-label indication is supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices. Generally, CMS requires such authoritative guidelines to be endorsed or recognized by United States government entities or medical specialty

organizations. We remind MAOs of the definition of a medically-accepted indication outlined in Chapter 6 of the Medicare Prescription Drug Benefit Manual, section 10.6.

10. Question: Are plans permitted to add/change step therapy mid-year? If so, what is the process for this?

Response: Yes, Medicare Advantage Organizations (MAO) are permitted to make mid-year changes to step therapy but only if such changes are consistent with the plan's Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) step therapy language and other statements made to beneficiaries. Note that ANOC and EOC can list each Part B drug that will be subject to step therapy or it can be more general.

11. Question: Can CMS clarify exception request requirements? What are the applicable adjudication timeframes?

Response: The timeframes set forth at 42 CFR §§ 422.568 and 422.572 apply to a request for a Part B drug. A request for a Part B drug is an organization determination request under Part C; therefore, the standard (14 calendar days) and expedited (72 hours) timeframes for Part C organization determinations apply to a request for a Part B drug.

MA-PD plans that offer all Medicare benefits under a single contract are required to coordinate those benefits when they receive a request for coverage for a drug that may be covered under Part A, Part B or Part D. In other words, an enrollee should not have to go through two separate exception processes for a Part B drug request even if the requested drug is subject to step therapy involving use of a Part D drug. If a request is for a Part B drug that is subject to step therapy, where the enrollee is required to use a Part D drug before coverage is allowed for a Part B drug, CMS expects the plan use the Part C organization determination, appeals and grievance procedures to handle these particular requests. Therefore, the plan must notify the enrollee of its decision as expeditiously as the enrollee's health requires, but no later than 14 calendar days for a standard request or 72 hours for an expedited request. In addition, CMS strongly encourages that MAOs expedite requests for exceptions in Part B, to align with the 72-hour adjudication timeframe for standard requests and 24 hours for expedited requests in Part D.