10.6 - Medically-Accepted Indication

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Section 1860D-2(e)*(4)* of the Act *defines* "medically-accepted indication," *in part* by reference to section 1927(k)(6) of the Act, to any use of a covered Part D drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. The *recognized* compendia are:

I. American Hospital Formulary Service Drug Information, *and*
II. DRUGDEX® Information System.

The definition of medically accepted indication also means, in the case of a covered Part D drug used in an anticancer chemotherapeutic regimen, the definition of medically accepted indication in section 1861(t)(2)(B) of the Act. Thus, Part D sponsors will be required to thoroughly understand and apply Part B's definition of an anti-cancer chemotherapeutic regimen, utilize Part B compendia, and consider peer reviewed medical literature when necessary. Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 50.4.5 (http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf) will be the authoritative guidance for Part D sponsors in their consideration of medically-accepted indications for Part D anti-cancer chemotherapeutic claims.

Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for medically-accepted indications *using the tools and data available to them to make such determinations. Part D sponsors must reference all CMS recognized compendia to determine whether there are any supportive citations, prior to determining that a drug is not being used for a medically-accepted indication.* Part D sponsors may rely on utilization management policies and procedures, *approved by CMS where required (see section 30.2.2.1),* to make such determinations. *Dispensing pharmacists* are not required to contact each prescriber to verify a prescription is being used for a medically-accepted indication.

Also, medically-accepted indication refers to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication. Part D sponsors may have dose limitations based on FDA labeling, but an enrollee may request (and be granted) an exception to a dose restriction through the formulary exception process based on medical necessity criteria.

Additionally a Part D drug must be used for a medically-accepted indication that facilitates the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (except for Part D vaccines). Consequently, if a drug works on medical equipment or devices and is not used for a medically-accepted indication of therapeutic value on the body, it cannot satisfy the definition of a Part D drug. For example, a heparin flush is not used to treat a patient for a medically-accepted indication, but rather to dissolve possible blood clots around an infusion line. Therefore, heparin's use in this instance is not therapeutic but is, instead, necessary to make durable medical equipment work. *Heparin* would therefore not be a Part D drug when used in a heparin flush.

Utilization management edits should be applied to drugs that are likely to be used for indications that are excluded from Part D coverage or that are not medically accepted in the sponsor's experience or as directed by CMS. While CMS would not expect edits to be universally applied to check whether every drug or most drugs are being used for medically-accepted indications, Part D sponsors remain responsible for ensuring that Part D drugs are only covered when used for medically-accepted indications. Therefore, all Part D sponsors should consistently utilize prior authorization (PA) for those drugs with the highest likelihood of non-Part D covered uses, as detailed in section 30.2.2.3 unless plans are able to reliably use tools other than PA to determine appropriate coverage for the drug.

10.6.1 - Retrospective Determination of a Medically-Accepted Indication

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Part D sponsors may retrospectively identify and confirm – either as part of their retrospective review programs required under 42 CFR *§*423.153, or incident to another utilization management review – that a dispensed drug*, including when dispensed as a transition fill,* was not prescribed for a medically-accepted indication for a particular individual (see the example below, in which this occurred because a dosage issue resulted in the case being flagged).

> Example: An individual receives a prescription and takes *the* drug within a common dosing regimen (i.e., one tablet daily). Several months later, that individual's physician writes a new prescription for an increased dosage of that drug. The second prescription triggers a quantity limit *claim edit* (for example, based on safety limits)*. A*s a result, the individual's physician *requests a coverage determination from the plan and* submits evidence to support an exception to the quantity limit. Based on that evidence, the Part D sponsor makes a determination that the drug was not prescribed for a medically-accepted indication.

When it was not reasonable to expect a Part D sponsor to require prior authorization to ensure a drug is being used for an accepted medical indication, CMS would not expect the sponsor to recover payments made to pharmacies or attempt to obtain reimbursement from enrollees. However, *when retrospective review of point of sale claims adjudication determines that a drug was dispensed for a non-medically-accepted indication, the PDE should be deleted and accumulators adjusted. (Sponsors should additionally reference all applicable PDE guidance and, when applicable, guidance in the Prescription Drug Benefit Manual, chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals, regarding required notices for coverage determinations, available at* https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip*).*