Essential Health Benefits Prescription Drug Standard

Issue No. 2 – Exceptions Process

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Introduced by the Affordable Care Act (ACA), Essential Health Benefits (EHB) are a set of ten health care service categories that plans must cover.[1] One of the ten categories of benefits is prescription drugs.

On February 20th, 2015, the Department of Health and Human Services (HHS) issued the Notice of Benefit and Payment Parameters for 2016 final rule (Final Rule 2016), which finalized changes to the EHB standard.[2] The Final Rule 2016 significantly modified the EHB prescription drug requirements.

This fact sheet, focusing on the prescription drug **exceptions process**, is part of a series of NHeLP fact sheets describing the EHB prescription drug standard. Additional fact sheets in this series examine formulary transparency, the use of the United States Pharmacopeia to establish minimum coverage standards, Pharmacy and Therapeutics (P&T) Committees, and new restrictions on mail-order only pharmacies.

Background - Exceptions Process

Health plans providing EHBs must have an exceptions process that allows an enrollee to request and gain access to clinically appropriate drugs that are not included in the plan's formulary.[3] Non-formulary prescription drugs available to enrollees through the exceptions process can be a critical component of the enrollee's treatment plan. For example, cancer patients often require the use of a health plan's exceptions process to "obtain products and services necessary to treat their condition."[4]

Currently, plans must have an *expedited exception* request process for exigent circumstances when an enrollee is suffering from a health condition that may seriously jeopardize his/her life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug.[5] Enrollees requesting an *expedited exception* must be notified of the coverage determination no later than 24 hours following receipt of the request. Health plans granting an exception

based on exigent circumstances must provide coverage of the prescription drug for the duration of the exigency.[6]

Change/Clarification

HHS revised the exceptions process for prescription drugs in order to establish a more uniform process across plans and issuers. HHS clarified that the exceptions process is different from the internal claims and appeals process for enrollees receiving an adverse benefit determination.[7] While the adverse benefit determination process is for a drug that is included in the plan's formulary drug list, the exceptions process is for non-formulary drugs.

The *expedited exception* process (described in the section above) continues to apply. Effective plan years beginning on or after January 1, 2016, health plans must also have a *standard exception* process for non-exigent circumstances and make a coverage determination and notify enrollees no later than 72 hours following receipt of the request. If the request is approved, the non-formulary drug must be covered for the duration of the prescription, including refills. This means enrollees will not have to repeatedly make requests to access a refill for a prescription drug obtained through the standard exceptions process.

For plan years beginning on or after January 1, 2016, if a health plan denies an exception request for a non-formulary drug (either an expedited or standard request), the health plan must have a process for a secondary external review by an independent review organization.[8] The same timing that applies to the initial process applies to the external review; therefore a determination must be made within 24 hours following receipt of the *expedited exception* request and within 72 hours following receipt of the *standard exception* request.[9] If the request is approved at the external review level, the health plan must provide coverage of the non-formulary drug for the duration of the prescription (including refills) for a *standard exception* and for the duration of the exigency for an *expedited exception*.[10] Health plans are not required to begin the external review process unless there is a request for such review by an enrollee following the denial of the original exceptions request.

HHS clarified that health plans must treat drugs covered through the exceptions process as EHBs and, therefore, count any cost-sharing for an approved drug towards a plan's annual limitation on cost-sharing and when calculating the plan's actuarial value.[11]

Advocacy Opportunities

- Ensure your state adopts the new federal prescription drug exceptions process standards.

- Monitor compliance with the exceptions process requirements. In the preamble to the Final Rule 2016, HHS addressed some of the concerns raised by consumer groups in comments to the proposed rule and provided the following guidance:[12]

    - The exceptions review process must begin following the receipt of sufficient information, which means health plans should not request irrelevant or overly burdensome information to begin the process.
    - Following a favorable decision on the standard or external review process, enrollees must be provided access to a non-formulary prescription drug without ***unreasonable*** delay.
    - Health plans must provide clear information and instructions on how to use the exceptions process:
        - HHS expects health plans, at a minimum, to update certificates of coverage to reflect the availability of the exceptions process and to provide enrollees, their designees, and providers with instructions on how to use the process.
        - Health plans must be equipped to accept prescription drug exceptions requests in writing, electronically and telephonically.

      Advocacy Tip: Ensure health plans are providing information about the availability of the exceptions process in plain English and using formats accessible to individuals with disabilities and/or limited English proficiency.

- Track whether there are additional exceptions process requirements that would be helpful to your client community, such as requiring coverage of the non-formulary drug during the review process. It will be important to let HHS know how the exceptions review process is working and where improvements are needed.

- Let NHeLP know if you see issues with the prescription drug exceptions process or any other prescription drug access issues.

NOTE: Contraceptive Coverage

Health plans subject to EHB requirements must also cover all Food and Drug Administration (FDA) approved contraceptive methods without cost-sharing as preventive services.[13] Under these rules, if a woman's provider determines that the specific contraceptives covered without cost-sharing in the plan formulary are medically inappropriate for her, the plan must have a waiver process in place to ensure that she can obtain the appropriate contraceptive without cost-sharing.[14] In addition to the advocacy opportunities listed above, advocates should monitor compliance with the contraceptive coverage requirement to ensure that all FDA-approved contraceptive methods are covered without cost-sharing or delay.

Conclusion

Beginning in 2016, health plan enrollees will have access to both an expedited and standard exceptions process, as well as an external review. These changes to the prescription drug exceptions process are a significant step forward. Advocates will have to monitor compliance with the new requirements to ensure enrollees have access to the prescription drugs they need. The new exceptions process requirements demonstrate the importance of advocacy efforts, so it will be important to track any issues with the exceptions process and lay the groundwork for future improvements in EHB prescription drug standards.

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[1] The ten EHB statutory categories of benefits are: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services (including chronic disease management); and pediatric services, including oral and vision care. The EHB requirement applies to non-grandfathered health plans offered in the individual and small group markets (both inside and outside the Marketplace). This fact sheet focuses on EHBs as they apply to the private market.

[2] HHS Notice of Benefit and Payment Parameters for 2016 Final Rule, 80 Fed. Reg. 10,750 (Feb. 27, 2015) (to be codified at 45 C.F.R. pts 144, 147, 153, 154, 155, 156, and 158), *available at* http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf [hereinafter Final Rule 2016].

[3] 45 C.F.R. § 156.122(c).

[4] American Cancer Society Cancer Action Network, Re: CMS-9944-P – Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters for 2016 (Dec. 22, 2014) *available at* http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0209.

[5] 45 C.F.R. § 156.122(c)(1)(i).

[6] *Id.* § 156.122(c)(1)(iii).

[7] Final Rule 2016, *supra* note 2, at 10,818; *see also* 45 C.F.R. § 147.136 (describing the internal claims and appeals and external review process which applies to drugs on a plan's formulary drug list).

[8] Final Rule 2016, *supra* note 2, at 10,818.

[9] *Id.*

[10] *Id.* at 10,818-19.

[11] *Id.* at 10,817-18.

[12] *Id.* at 10,818.

[13] 45 C.F.R. § 156.115(a)(4); U.S. Dep't of Health and Human Srvcs., Health Res. and Srvcs. Admin., *Women's Preventive Services Guidelines* (Aug. 1, 2011), *available at* http://www.hrsa.gov/womensguidelines/.

[14] U.S. Dep't of Health and Human Srvcs., U.S. Dep't of Labor, and U.S. Treasury, FAQs on Affordable Care Act Implementation XII, Question 14 (Feb. 20, 2013), *available at* http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.