AIMEDALLIANCE

September 1, 2023

Michael Humphreys
Commissioner
Insurance Department, Commonwealth of Pennsylvania
1326 Strawberry Square
Harrisburg, PA 17120

Re: Commonwealth Essential Health Benefits Benchmark Plan—Public Comment Period; Notice 2023-14

Dear Commissioner Humphreys:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We appreciate the opportunity to provide input on the Commonwealth's essential health benefits (EHB) benchmark plan. As explained in further detail below, Aimed Alliance strongly urges the Commonwealth's Department of Insurance to:

(1) Ensure specialty medications are considered part of the definition of prescription drugs as an EHB; and
(2) Ensure consumers have access to non-formulary treatments through proper application of the exception process.

I. The Definition of Prescription Drugs as an EHB Must Include Specialty Drugs

The Patient Protection and Affordable Care Act (ACA) requires health plans cover 10 EHBs, one of which is prescription drugs. The ACA specifies that to satisfy the coverage requirement for prescription drugs under the ACA the health plan must cover "at least the greater of (1) one drug in every USP category and class; or (2) the same number of prescription drugs in each category and class as the benchmark plan."[1] This phrase establishes a minimum standard for prescription drug coverage as an EHB, creating a floor rather than a ceiling.[2]

The ACA requires all cost-sharing for the cost of an EHB item or service to count towards meeting the consumers' annual out-of-pocket limits.[3] However, HHS has stated that plans could impose certain limits on benefits "that do not fall within the definition of EHB."[4] The guidance also stated that plans may only modify the definition of an EHB in a manner "that is ***authorized by the Secretary of HHS."***[5]

[1] 42 C.F.R. 156.122.
[2] 2016 NBPP, https://www.federalregister.gov/ documents/2015/02/27/2015-03751/patient-protectionand-affordable-care-act-hhs-notice-of-benefit-andpayment-parameters-for-2016.
[3] Affordable Care Act, https://www.healthcare.gov/glossary/affordable-care-act/.
[4] CMS, Frequently Asked Questions on Essential Health Benefits Bulletin, https://perma.cc/HCH7-6AYA at p. 4
[5] *Id.*

While the ACA does not define the term "prescription drugs," the ACA regulation governing prescription drugs as an EHB refers to "FDA-approved drugs."[6] The FDA defines a "prescription drug" as "any human drug required by Federal law or regulation to be dispensed only by a prescription"[7] Likewise, the plain meaning of the word "prescription drug" is a "drug that can be obtained only by means of a [health care practitioner's] prescription."[8] Moreover, HHS has stated that the definition for prescription drugs as an EHB can exclude (1) medications used for abortion; and (2) brand name drugs that have generic alternatives available.[9]

Despite these narrow carveouts, some health plans have argued they can exclude specialty drugs as non-EHBs, and thereby accept cost-sharing from the patient and not count it towards their deductible or annual out-of-pocket limit.

Specifically, these health plans have used two main arguments to justify this interpretation. First, these programs allege they are permitted to carve out specialty drugs from the definition of prescription drugs as an EHB.[10] Second, these programs allege they are only required to cover the minimum number of drugs in a class or category and everything else can be deemed a non-EHB. Both interpretations are improper. As such, the Commonwealth's Department of Insurance should explicitly ensure that specialty drugs that are deemed medically necessary are considered EHBs.

A. Specialty Drugs Are Prescription Drugs

Specialty drugs play a pivotal role in the treatment of various medical conditions, including rare diseases, autoimmune disorders, and certain types of cancer. Due to their complex nature and specific administration requirements, specialty drugs are often more expensive and placed on the highest cost-sharing tier. As a result, patients who rely on these treatments can face significant financial challenges in accessing these treatments.

Carving out specialty drugs from the definition of a prescription drug as an EHB is inconsistent with HHS guidance. Specialty medications should be considered prescription drugs because specialty medications require a prescription in order to be dispensed or administered, thus satisfying the FDA's definition of prescription drugs.[11] Furthermore, these drugs are not excluded from the ACA's regulations as many of these drugs have no generic equivalents available, and are not typically used for abortion. Therefore, specialty medications are within the EHB category of "prescription drugs."

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[6] 42 C.F.R. 156.122(a). This regulation states that in order for prescription drugs to be considered an EHB, the plan must use a pharmacy and therapeutic (P&T) committee that meets certain standards. These standards include a reviewof new and existing FDA-approved drugs. As such, the term "prescription drugs" likely refers to FDA-approved drugs.
[7] 21 C.F.R. 205.3(e)
[8] *Prescription Drug,* https://www.merriam-webster.com/dictionary/prescription%20drug .
[9] HHS, FAQ About Affordable Care Act, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-andFAQs/aca_implementation_faqs19#ftn8
[10] SaveOnSp, https://vimeo.com/513414094
[11] 21 C.F.R. 205.3(e)

B. The Benchmark Plan is Intended to Be a Floor Not a Ceiling for Prescription Drug Coverage

Health plans have also argued that they are only required to cover the minimum number of drugs in a class or category and everything in addition is considered a non-EHB.[12] Again, this is inconsistent with HHS guidance.

In 2016, HHS confirmed that all medications in addition to the minimum number covered in the benchmark plan should be treated as EHBs. Specifically, HHS stated that "plans are permitted to go beyond the number of drugs offered by the benchmark without exceeding EHB. Therefore, if the plan is covering drugs beyond the number of drugs covered by the benchmark, ***all of these drugs are EHB and must count towards the annual limitation on cost sharing***."[13] This position was also reaffirmed by HHS in the NBPP 2020.[14]

Moreover, HHS has explicitly provided a pathway for non-formulary drugs to be treated as EHBs under the exception process. Under the exception process, plans must ensure an enrollee is able to "gain access to clinically appropriate drugs not otherwise covered by the health plan"[15] and that "[i]n the event that an exception request is granted, the plan must treat the excepted drug(s) as an [EHB], including by counting any cost-sharing towards the plan's annual limitation on cost-sharing."[16] Thus, it is inconsistent with the ACA's exception process to deem non-formulary treatments that exceed the benchmark plan as non-EHBs when these medications have been deemed medically necessary.

By explicitly incorporating specialty drugs into the EHB for prescription medications, this misinterpretation of the EHB requirements by plans would be eliminated, thereby requiring health plans to count all cost-sharing payments towards the patient's annual out-of-pocket maximum. This action would ensure patients can access the required treatments without encountering discriminatory practices that undermine their financial stability and impede their ability to manage their health effectively.

II. Ensure Plans Uphold the Exception Process for EHBs

As explained above, the ACA requires that all ACA regulated health plans provide an exception process to ensure an enrollee is able to "gain access to clinically appropriate drugs not otherwise covered by the health plan"[17] and that "[i]n the event that an exception request is granted, the plan must treat the excepted drug(s) as an [EHB], including by counting any cost-sharing towards the plan's annual limitation on cost-sharing."[18]

However, recently Aimed Alliance has learned that health plans are refusing to provide a proper exception process to access non-formulary EHBs. Specifically, ACA plans are informing

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[12] IPBC and SaveonSP Training-20210216 1901-1, https:// vimeo.com/513414094.
[13] 2020 NBPP, *Final Rule,* govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf at p. 69 (emphasis added).
[14] *Id.*
[15] 45 CFR § 156.22 (b).
[16] 45 CFR § 156.22 (b).
[17] 45 CFR § 156.22 (b).
[18] 45 CFR § 156.22 (b).

enrollees that their exception requests for their non-formulary treatments are denied because the drug is excluded by the plan (i.e., not on the formulary), and that the health plan benefit states that prescription drugs not on the drug formulary are excluded from coverage. As such, the enrollee is told if they would like to access the medication, they are responsible for 100 percent of the cost, and it will not count towards their annual limits on cost-sharing.

This is the exact situation the ACA's exception process intended to avoid. Under this interpretation, an enrollee would never be able to access a non-formulary treatment, even when medical necessity is established. Moreover, the ACA requires health plans to review the exception request under a *medical necessity review standard.* A cursory review that only considers covered and non-covered benefits is circular and does not satisfy the ACA requirement.

As such, we urge the Commonwealth's Department of Insurance to carefully monitor how health plans cover prescription drugs as an EHB and ensure access to non-formulary treatments as EHBs under the exceptions process.

III. Conclusion

In conclusion, we support the efforts of the Department to update the Commonwealth's EHB benchmark plan; and we appreciate the opportunity to provide our input on this critical matter. We urge the Department to ensure medically necessary specialty drugs are considered EHBs under the benchmark plan. Thank you for your time and consideration of our concerns.

Sincerely,

Ashira Vantrees
Counsel