

340B/High-Cost Drugs Impact Report

Summary

At least 180 days before any restriction or limitation is implemented on an eligible hospital's access to the discounted purchase of prescription drugs to the full extent permitted under section 340B of the federal Public Health Service Act, as codified under 42 U.S.C. § 256b, the Secretary of Health and Human Services is required to submit a report to the Joint Committee on Health Care Financing and the Senate and House Committees on Ways and Means detailing:

- (A) the proposed restriction or limitation;
- (B) the anticipated aggregate savings to the Commonwealth;
- (C) the estimated fiscal impact of the restriction or limitation on each affected hospital; and
- (D) the manner in which the Secretary plans to mitigate the fiscal impact, which may include measures to maintain savings already achieved by providers under said 42 U.S.C. § 256b.

The MassHealth program intends to limit payment for twenty drugs for MassHealth members if purchased through the 340B Drug Pricing Program to allow the Commonwealth to benefit from value-based contracts entered into by MassHealth. These twenty drugs consist of eleven drugs that are already excluded from coverage if purchased through the 340B Drug Pricing Program, and the nine new drugs excluded from coverage if purchased through the 340B Drug Pricing Program described below. MassHealth will continue to pay for these twenty drugs for MassHealth members when purchased outside of the 340B Drug Pricing Program, and this policy will therefore not impact MassHealth member access to these drugs, or the ability of hospitals to receive payment for these drugs when purchased through the 340B program and provided to non-MassHealth patients. This report details the proposed limitation and its anticipated fiscal impact and mitigation.

(A) Proposed Restriction or Limitation

New 340 Drugs Excluded from MassHealth Coverage

MassHealth has designated the following nine drugs as non-payable when purchased through the 340B drug pricing program and provided to MassHealth members:

- Amtagvi (lifileucel)
- Beqvez (fidanacogene elaparvovec)
- Casgevy (exagamglogene autotemcel)
- Elevidys (delandistrogene moxeparvovec-rokl)
- Lenmeldy (atidarsagene autotemcel)

- Lyfgenia (lovotibeglogene autotemcel)
- Omisirge (omidubicel-only)
- Roctavian (valoctocogene roxaparvovec-rvox)
- Tecelra (afamitresgene autoleucel)

In accordance with 130 CMR 406.404(D): *Participation in the 340B Drug Pricing Program for Outpatient Pharmacy Services*, these drugs are high-cost drugs with a gross cost of \$100,000 or more per utilizer per year.

This policy has no impact on MassHealth's coverage of medically necessary drugs for MassHealth members. This policy affects only the method by which specific high-cost drugs may be purchased when provided to MassHealth members, and does not impact the use of 340B drugs for other patients.

MassHealth will implement this limitation no sooner than August 18, 2025.

(B) Anticipated Aggregate Savings to the Commonwealth

MassHealth has value-based payment (VBP) contracts tied to certain of these drugs and may enter into VBP contracts covering other such drugs where payment for the drug is tied to patient outcomes. VBP contracts allow drug manufacturers to stand behind their products and take financial responsibility for clinical outcomes. These VBP contracts protect the Commonwealth in the event the drugs do not perform as desired and therefore potential savings are dependent on actual clinical outcomes. MassHealth is unable to estimate such savings at this time, which will vary depending on the number of value-based contracts entered into and the clinical outcomes for patients.

(C) Estimated Fiscal Impact of the Restrictions or Limitations on each Affected Hospital

Each of the nine added drugs are already listed or will be listed on the MassHealth Acute Hospital Carve-Out Drugs List, and providers are reimbursed at their actual acquisition cost of the drug, regardless of method of purchase. This payment methodology will not change. Hospitals will pay more to purchase the drug outside of the 340B Drug Pricing Program but will be reimbursed at a corresponding higher amount. As such, any fiscal impact of this policy is limited to temporary cash-flow impact. There are, however, potential savings for the Commonwealth under the VBP contracts.

It is important to note that drug manufacturers are typically unwilling to pay rebates on drugs purchased through the 340B Drug Pricing Program, and states cannot collect the standard federal rebate on drugs purchased through the 340B program. Many manufacturers are also unwilling to pay state-only rebates, including value-based rebates, on a drug that does not have a standard federal rebate. Requiring these drugs to be purchased outside of the 340B program for MassHealth members allows the Commonwealth to benefit from the protections available through a value-based contract.

(D) How the Secretary Plans to Mitigate the Fiscal Impact, which may Include Measures to Maintain Savings Already Achieved by Providers under 42 U.S.C. § 256b.

The Secretary of Health and Human Services does not anticipate there will be a fiscal impact, so there will be no need to mitigate. MassHealth will provide notice to affected providers for input by provider bulletin and may adjust this policy if it is determined that there is a fiscal impact.