Michigan Department of Health and Human Services
Program Policy Division PO Box 30809
Lansing MI 48909

MDHHS
Michigan Department of Health & Human Services
GRETCHEN WHITMER, GOVERNOR | ELIZABETH HERTEL, DIRECTOR

November 25, 2025

<Provider Name>
<Provider Address 1>
<Provider Address 2>
<City> <State> zipcode5-zipcode4

Dear Provider:

RE: 340B Policy Reminder for Cell and Gene Therapy Access Model

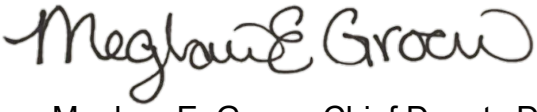
The Michigan Department of Health and Human Services (MDHHS) is participating in the national Cell and Gene Therapy (CGT) Access Model administered by the Center for Medicare and Medicaid Innovation (CMMI). The CGT Access Model supports state Medicaid program coverage of gene therapies delivered under Centers for Medicare and Medicaid Services (CMS) negotiated outcomes-based agreements. For more information on the CGT Access Model, visit: https://www.cms.gov/priorities/innovation/innovation-models/cgt. The initial focus of the model is on access to gene therapy treatments for people living with sickle cell disease.
The purpose of this letter is to remind providers of the 340B discount policy related to gene therapies for sickle cell disease—specifically Casgevy (exagamglogene autotemcel) and Lyfgenia (lovotibeglogene autotemcel) – and any future cell and gene therapies selected for the CGT Access Model.

Section 340B of the Public Health Service Act requires drug manufacturers to provide outpatient drugs at reduced prices to eligible organizations, while also protecting manufacturers from paying both a Medicaid rebate and a 340B discount on the same drug. Casgevy and Lyfgenia are administered in the inpatient setting. The 340B program does not apply to drugs used for inpatient individuals, even if they are directly reimbursed and considered “covered outpatient drugs” for purposes of the Medicaid Drug Rebate Program. Accordingly, Casgevy and Lyfgenia do not qualify for 340B discounts.

Because manufacturers are protected from paying both a Medicaid rebate and a 340B discount on the same drug, providers may not claim 340B discounts on future cell and gene therapies selected for the CGT Access Model. MDHHS will notify providers if additional cell and gene therapies are added to the CGT Access Model. For more information on submitting claims for drugs purchased through the 340B program, refer to the Billing and Reimbursement for Institutional Providers chapter in the MDHHS Medicaid Provider Manual.

An electronic version of this document is available at www.michigan.gov/medicaidproviders >> Policy, Letters & Forms.

Sincerely,



Meghan E. Groen, Chief Deputy Director
Health Services