Medicaid Coverage Practices for Approved Gene and Cell Therapies: Existing Barriers and Proposed Policy Solutions

The full article can be accessed here: https://www.cell.com/molecular-therapy-family/methods/fulltext/S2329-0501(23)00077-3

Improve federal guidance and transparency efforts supporting the implementation of statutory requirements

Issue additional guidance to states outlining current federal requirements for coverage to label

CMS should issue additional guidance to states reiterating the expectations of current requirements relating to coverage to label. This guidance could also identify products that recently received FDA approval, ensuring states are aware of potentially impactful products coming to market.

Reiterate current requirements for timely access to covered benefits

Congress should work with CMS to reinforce timely coverage of gene and cell therapy and limit the unnecessary and time-consuming demands for additional criteria to be met beyond the FDA-approved labeling. CMS should also consider reforms to prior authorization and pre-certification policies to minimize the burden on providers and patients and expedite decisions.

Establish clearer channels for stakeholders to report noncompliance with federal coverage rules

CMS should establish a clear method for patients, providers, manufacturers, and other members of the public to identify instances in which state policies relating to coverage of gene and cell therapy fall short of federal expectations.

Create a public dashboard

CMS should establish a public dashboard tracking coverage policies, denials, complaints, and discrepancies in coverage and reimbursement for each product across states. The information would be useful in quantifying the true scope of any problems or overly restricted coverage.

Consider federal audits

Congress should direct federal investigative agencies to conduct regular reviews of compliance with federal Medicaid coverage rules as new gene and cell therapies come to market. This review could be conducted by the Office of the Inspector General, the Government Accountability Office, or other federally supported entities tasked with tracking compliance with federal regulations.

Modify federal payment policies to support states in bearing the up-front costs of gene and cell therapies

Alternative payment options

Congress and CMS should work to advance novel payment arrangements such as value-based payment (VBP) or outcomes-based arrangements (OBAs) that spread the cost of therapies over time or tie reimbursement to outcomes. For instance, building on the CMS rule modifying current Best Price reporting requirements, and continuing to work with stakeholder to implement the proposed Centers for Medicare and Medicaid Innovation Cell and Gene Therapy Access Model.

Enhanced federal support

Congress should consider policies that would enhance the federal government's role in covering Medicaid costs of these therapies. The federal government generally has greater budget flexibility than states, putting the federal government in a more comfortable position to bear anticipated costs and spread risks. **The federal government, for instance, could increase its share of payments to states (the federal match percentage; FMAP) for new gene and cell therapies. Alternatively, the Medicaid and CHIP Payment and Access Commission considered establishing gene and cell therapy as a separate Medicaid benefit.**

Support states in integrating new gene and cell therapies into Medicaid benefits

Establish new mechanisms for states to preview gene and cell therapies coming to market

CMS should require or encourage states to adopt more standard processes for meetings between states and manufacturers to have productive preapproval conversations to prepare budgeting and coverage decisions for these therapies.

Provide states with a "best practices" guide for coverage of gene and cell therapy

CMS should provide states with guides or toolkits, similar to previous efforts, that can help states more seamlessly integrate these therapies into their benefit offerings.

The American Society of Gene & Cell Therapy is the primary professional membership organization for gene and cell therapy. The Society's members are scientists, physicians, patient advocates, and other professionals. Our members work in a wide range of settings including universities, hospitals, government agencies, foundations, and biotechnology and pharmaceutical companies.

For more information about cell and gene therapy payment policies, please contact advocacy@asgct.org.