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Agenda

• Vaccine Counseling for Medicaid and CHIP Beneficiaries
• SMDL: Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials
• CIB: Opportunities to Increase Enrollment in Medicare Savings Programs
• Oral COVID Drug Update
Importance of Vaccine Counseling

• As of May 2021, Medicaid and CHIP enrollment totaled 82.7 million individuals, including over 39 million children. Child enrollment in these programs represents about half of all children in America and represents approximately 47 percent of total Medicaid and CHIP enrollment.
  o Medicaid beneficiaries currently have some of the lowest COVID-19 vaccination rates.

• Vaccine counseling, provided separately from the actual delivery of a vaccine, can help address vaccine hesitancy by helping beneficiaries get their questions answered and receive additional information on vaccines from trusted providers.

• Recently, the FDA and CDC authorized and recommended the Pfizer-BioNTech COVID-19 vaccine for children age 5 and older, as well as Pfizer-BioNTech, Moderna, and Johnson & Johnson (Janssen) booster doses for all people age 18 and over.

• Coverage of vaccine counseling could help states increase COVID-19 vaccination rates for Medicaid and CHIP beneficiaries, including children. Survey data have shown that parents, many of whom are vaccinated for COVID-19 themselves, are hesitant to get their children vaccinated right away and that they are most comfortable getting their children vaccinated by their regular provider.

• AAP recommends that providers address parental concerns and questions regarding vaccines and that counseling is important to address parental anxiety and misinformation.
Vaccine Counseling as a Tool

- Currently, states can opt to cover vaccine counseling-only visits, during which vaccines are not delivered, in Medicaid and CHIP, and their expenditures on these visits are federally matched at the state’s applicable federal match rate.

- Vaccine counseling is a tool available for all vaccines, and is particularly important during the COVID-19 public health emergency (PHE) as families look to catch up on routine vaccines and well-child visits.

- As outlined in the chart, preliminary data show that vaccinations among Medicaid and CHIP beneficiaries under age 19 declined for all vaccines except influenza during the COVID-19 PHE period compared to prior years.

Notes: These data are preliminary. Data are sourced from the T-MSIS Analytic Files v5 in DataConnect using final action claims. They are based on July 2021 T-MSIS submissions with services through the end of June 2021. Recent dates of service have very little time for claims runout and we expect large changes in the results after each monthly update. Because data for June 2021 are incomplete, results are only presented through May 31, 2021. The COVID-19 PHE period includes data for March 2020 through May 2021. The pre-PHE average is the average of all values for that month in the years that predate the COVID-19 PHE, including data from January 2018 through February 2020.
Medicaid: Pediatric Vaccine Counseling

Section 9811 of the American Rescue Plan Act of 2021 (ARP) requires state Medicaid programs to cover COVID-19 vaccine administration without cost sharing and makes 100% federal match available for state Medicaid expenditures on COVID-19 vaccine administration.

• CMS interprets the Medicaid Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit to require states to cover visits in which a child under age 21 and/or caregivers are counseled about a vaccine, but the child does not receive the vaccine because the child and/or caregivers are not ready to consent to its receipt.

• CMS interprets the ARP references to the administration of a COVID-19 vaccine, including in § 1905(a)(4)(E) and (hh) of the Social Security Act to include COVID-19 vaccine counseling visits during which no COVID-19 vaccine is injected when these visits are covered for children under age 21 as part of the EPSDT benefit. This means that CMS will federally match state expenditures on these visits at 100%. This policy applies only to COVID-19 vaccine counseling-only visits that are covered as part of the Medicaid EPSDT benefit.

• CMS’s interpretation of the ARP provisions is based on the overall structure and context of the Medicaid statute. In particular, states are required to cover “health education” as part of the EPSDT benefit, under § 1905(r)(1)(B)(v) of the Social Security Act. There is no comparable benefit or coverage requirement for individuals in Medicaid age 21 or over, or in a separate CHIP.
Medicaid: Pediatric Vaccine Counseling (cont’d)

• 100% federal match for state Medicaid expenditures on COVID-19 vaccine counseling-only visits under the ARP and EPSDT requirements will be available for the ARP FMAP period, which is April 1, 2021 through the last day of the first quarter that begins one year after the last day of the COVID-19 emergency period.

• After the ARP FMAP period expires, federal matching for state Medicaid expenditures on COVID-19 vaccine administration, including on these counseling visits, will revert to the regularly applicable percentage.

Implication for Other Vaccines

• Under CMS’s updated interpretation of EPSDT, states must cover stand-alone vaccine counseling visits for all pediatric vaccines under EPSDT, regardless of federal matching percentage.
What Date Is 100% Match Available for Pediatric COVID-19 Vaccine Counseling?

• States currently covering stand-alone pediatric COVID-19 vaccine counseling in Medicaid as part of EPSDT will be able to retroactively adjust claims back to April 1, 2021 to receive 100% federal match for these expenditures.

• States newly implementing Medicaid coverage of stand-alone pediatric COVID-19 vaccine counseling as part of EPSDT will be able to claim 100% federal match for their expenditures on this coverage on or after April 1, 2021.
  • States can request section 1135 waiver authority to enable a retroactive effective date for state plan amendments implementing this new coverage.

• CMS will work to ensure appropriate oversight of states’ claiming and allocation methodologies, and will place special emphasis on state expenditures claimed at 100% federal match while conducting quarterly and annual financial reviews.
Vaccine Counseling Outside of EPSDT in Medicaid

• Currently, states can opt to cover vaccine counseling-only visits, in which vaccines are not delivered, for all Medicaid populations, including medically needy and optional categorically needy adults, under an array of Medicaid benefits. States can continue to opt to cover these visits for beneficiaries not eligible for EPSDT.

• Unless state expenditures on these visits are for stand-alone COVID-19 vaccine counseling covered as part of EPSDT (which states must now cover), they will be federally matched at the regularly applicable federal match rate, not at 100%.
What is Needed from States?

• CMS will provide technical assistance on how to change or add Medicaid coverage or payment methodologies for stand-alone vaccine counseling for all populations, including populations eligible for EPSDT. This will include technical assistance on possible state plan amendments.

• States may also need to make required systems changes and issue changes to Medicaid provider manuals and claiming instructions.
Vaccine Counseling in CHIP

• CMS does not interpret the references to COVID-19 vaccine administration that were added to the CHIP statute by § 9821 of the ARP to include stand-alone counseling visits about the COVID-19 vaccine for CHIP beneficiaries. States can opt to cover stand-alone COVID-19 (and other) vaccine counseling visits for children and pregnant adults enrolled in CHIP, but are not required to do so, and their expenditures on these visits will not be federally matched at 100%.

• No state plan amendment is required to cover stand-alone vaccine counseling in CHIP.
Clinical Trial Coverage Mandates

- Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) amended section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit for routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials.
- The mandate becomes effective on January 1, 2022.
Routine Patient Costs

- Routine patient costs includes any item or service provided to the individual under the qualifying clinical trial, including:
  - Any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan or waiver, including a demonstration project under section 1115 of the Act.
  - Any item or service required solely for the provision of the investigational item or service that is the subject of such trial, including the administration of such investigational item or service.
Routine Patient Costs

- Routine patient costs do not include-
  - Any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project.
Some examples of routine costs in a clinical trial could include:

- Otherwise covered physician services or
- Laboratory services
An example of what is not covered under routine patient costs could include:
  - Medical imaging scans for purposes of clinical trial data collection, to the extent they are not used for the direct clinical management of the beneficiary.
Qualifying Clinical Trial

- In order to receive coverage, routine patient costs for items and services must be furnished in connection with participation in a qualifying clinical trial.

- The term ‘qualifying clinical trial’ means a clinical trial (in any clinical phase of development) that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition as further described in section 1905(gg)(2)(A).
A determination for coverage for an individual participating in a qualifying clinical trial—

- shall be expedited and completed within 72 hours;
- shall be made without limitation on the geographic location or network affiliation of the health care provider;
- shall be based on attestation; and
- shall not require submission of the protocols of the qualifying clinical trial, or any other documentation that may be proprietary or determined by the Secretary to be burdensome to provide.
State Plan Amendments (SPAs)

- States will need to submit a new SPA at section 3.1A and 3.1B to effectuate this new coverage requirement under section 1905(a)(30), effective January 1, 2022.
- A SPA template is currently under development.
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Questions