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Agenda

• Consumer Research on Unwinding Phase I: Preventing Churn
• Latest Updates from CDC’s COVID-19 Vaccine Task Force
• State Flexibilities to Determine Financial Eligibility for Individuals in Need of HCBS
• Vaccine Toolkit Updates
• Section 9817 Updates
• Open Mic Q and A
Consumer Research on Unwinding Phase I: Preventing Churn
The Research

• Qualitative in-depth interviews with 49 people/caregivers receiving Medicaid/CHIP
  – Included representation of:
    • MAGI, Dual-eligible, Disabled, and Parents
    • People in states with low or high ex-parte
  
• Discussion on enrollment and re-enrollment experiences and expectations.

• Reviewed straightforward messaging on:
  – what to do (keep you address updated, look in the mail for an application from your state).
  – Contextual information on why this is important now, including explanation on rules impacted by the Public Health Emergency (PHE).
Key Takeaways – *Audiences*

- Medicaid MAGI and CHIP enrollees often rely on other social programs and health care providers for enrollment.
  - There appears to be strong partnerships with SNAP, WIC, housing, head start, and healthcare providers (e.g., hospitals, clinics, doctor’s offices). Joint efforts with these organizations likely to enhance a campaign’s effectiveness.

- Medicare and Medicaid dually-eligible people tend to be confused by the general enrollment process between Medicare and Medicaid. Many were unclear how they enrolled in Medicaid. Partner with their Medicare plans.

- Those with disabilities have a laser focus on SSA for all information.
Key Takeaways - **Experiences**

- Most enrollees are not concerned or wondering about reenrollment.
- Many, almost half, responded that they have reenrolled since March 2020.
- Many respondents look to the states for “official” mail and claim they keep their addresses up-to-date.
  - Many appreciate the opportunity to sign up for email and text alerts, but don’t want it to replace mail.
- A group of respondents say they know it is time to reenroll when their card no longer works at their doctor’s office.
- Allow time for participants to take action, some see re-enrollment as time consuming.
  - Although, several also mentioned the process is not difficult.
Key Takeaways - Messaging

• Keep it simple:
  – Your Medicaid coverage needs to be renewed next year *(if possible, use precise timing)*.
  – **What you can do now:** Update your address – if you’ve moved, let [State] Medicaid know your updated address, so they can contact you about your renewal.
  – **What you can do later this year:** Check your mail – [State] Medicaid will either send you a letter confirming your coverage is renewed or a renewal form you need to complete.
Key Takeaways - *Messaging*

- Avoid vague timing (“this year”). It causes anxiety among about half the respondents who will call state helpline.
- Avoid mentioning “autorenewal might occur” as it causes confusion. Autorenewal can be mentioned to inform a person “you have been auto-renewed.”
- In direct-to-consumer outreach, we may not need to refer to the PHE, but if we do, mention COVID. PHE has little meaning to this audience.
- Avoid saying they haven’t had to reapply, as many have actually had the experience of reapplying.
Thank You

Research conducted by ANR Research, Richmond VA in partnership with CMS’ Office of Communication
Latest Updates from CDC’s COVID-19 Vaccine Task Force

Evelyn Twentyman, MD MPH
CMCS All-State
February 22, 2022
COVID-19 primary series vaccination is recommended for everyone ages 5 years and older in the United States for the prevention of COVID-19.

- This includes people with underlying medical conditions.
- People with moderate or severe immunocompromise have additional considerations and need more doses than most people.

In most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 Vaccine for primary and booster vaccination.
Latest Updates for People with Moderate to Severe Immunocompromise
People with Moderate or Severe Immune Compromise

- People with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19.
- People with immunocompromising conditions may not mount a protective immune response after initial vaccination and protection may wane over time.
- COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people.
People with Moderate or Severe Immune Compromise

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (HCT) (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory
HCT and CAR-T-cell Recipients

- HCT and CAR-T-cell recipients who received doses of COVID-19 vaccine prior to or during treatment with an HCT or CAR-T-cell therapy should be revaccinated with a primary vaccine series – Preferably with an mRNA vaccine (3 doses) regardless of vaccine issued for initial primary vaccination – At least 3 months (12 weeks) after transplant or CAR-T-cell therapy
Updated COVID-19 Vaccine Recommendations for People Who Are Moderately or Severely Immunocompromised

- **mRNA COVID-19 vaccine primary series recipients:**
  - Shortened interval between 3-dose primary series completion and booster dose from 5 months → **3 months**

- **Janssen COVID-19 vaccine recipients**
  - Recommended to receive a 2\(^{\text{nd}}\) (additional) dose using an mRNA COVID-19 vaccine at least 28 days after the Janssen dose, followed by a booster dose 2 months after the mRNA dose*

- **Providers of immunocompromised patients:**
  - On a case-by-case basis, may administer mRNA vaccines outside of the FDA and CDC dosing intervals based on clinical judgement when the benefits of vaccination are deemed to outweigh the potential and unknown risks for the recipient

* New appendix provides guidance for people who already received a booster dose prior to the recommendation for a 2\(^{\text{nd}}\) dose using an mRNA vaccine
Clarification of Existing COVID-19 Vaccine Recommendation for Those Who Previously Received mRNA Vaccines

People ages 12 years and older with moderate or severe immune compromise at the time of primary vaccination should receive a total of 4 mRNA COVID-19 vaccine doses:

- **Dose 1**: Pfizer
  - 21 days
- **Dose 2**: Moderna
  - 28 days
- **Dose 3**: Moderna
  - 28 days 3 months
- **Dose 4 (Booster)**:
  - 3 months
**Updated COVID-19 Vaccination Schedule for People Who Are Moderately or Severely Immunocompromised**

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>1st dose</th>
<th>2nd dose (21 days after 1st dose)</th>
<th>3rd dose (at least 28 days after 2nd dose)</th>
<th>Booster dose* (at least 3 months after 3rd dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>1st dose</td>
<td>2nd dose</td>
<td>3rd dose</td>
<td>Booster dose*</td>
</tr>
<tr>
<td>(ages 5 years and older)</td>
<td></td>
<td>(21 days after 1st dose)</td>
<td>(at least 28 days after 2nd dose)</td>
<td>(at least 3 months after 3rd dose)</td>
</tr>
<tr>
<td>Moderna</td>
<td>1st dose</td>
<td>2nd dose</td>
<td>3rd dose</td>
<td>Booster dose*</td>
</tr>
<tr>
<td>(ages 18 years and older)</td>
<td></td>
<td>(28 days after 1st dose)</td>
<td>(at least 28 days after 2nd dose)</td>
<td>(at least 3 months after 3rd dose)</td>
</tr>
<tr>
<td>Janssen</td>
<td>1st dose</td>
<td>2nd dose using mRNA vaccine †</td>
<td>3rd dose</td>
<td>Booster dose*</td>
</tr>
<tr>
<td>(ages 18 years and older)</td>
<td></td>
<td>(at least 28 days after 1st dose)</td>
<td>(at least 28 days after 2nd dose)</td>
<td>(at least 2 months after 2nd dose)</td>
</tr>
</tbody>
</table>

*Only people ages 12 years and older are eligible for booster doses. Any COVID-19 vaccine can be used for the booster dose in people ages 18 years and older, though mRNA vaccines are preferred. For people ages 12–17 years, only Pfizer-BioNTech can be used. People ages 5–11 years should not receive a booster dose.

†Only Pfizer-BioNTech or Moderna COVID-19 Vaccine should be used
Latest Updates for People Who Received Passive Antibody Products
Passive Antibody Products

- Study among nursing home residents and staff demonstrated that recipients of bamlanivimab mounted a robust immune response to mRNA vaccination, regardless of age, risk category, or vaccine type.
- Although antibody response was numerically lower in people who received monoclonal antibodies, they were still considered to be high and the clinical significance of the reduction is unknown.
- There was no correlation between interval to COVID-19 vaccination and neutralizing titers in recent monoclonal antibody recipients.
- Programmatically, there are challenges to current intervals between receipt of monoclonal antibodies and COVID-19 vaccination.
- Getting vaccinated is a priority.

Passive Antibody Products

**Previous guidance**

Defer COVID-19 vaccination for:
- 30 days if product was used for post exposure prophylaxis
- 90 days if product was used for treatment
- No guidance for pre-exposure prophylaxis

**Revised guidance**

- No recommended deferral period
- However, tixagevimab/cilgavimab (EVUSHELD™) should be deferred for at least two weeks after vaccination

Thank you

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Benefit-risk to inform decision making during the Janssen COVID-19 vaccine pause

Benefit-risk review of all vaccine-associated events (TTS, GBS, myocarditis)

Benefit-risk of Janssen COVID-19 vaccine in the context of additional data, sufficient vaccine supply

April 2021

July 2021

December 2021

- Additional case review and ongoing safety surveillance identified cases (previous and newly occurring) of TTS, including deaths, after receipt of Janssen COVID-19 vaccine
- No longer in the setting of limited mRNA COVID-19 vaccine supply in the US
- ACIP December 16 Vote: mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for the prevention of COVID-19 for those aged ≥18 years
Three Dose Primary Series for Children 5–11 Years Who are Immunocompromised

- Vaccine effectiveness is lower among patients with immunocompromise¹
- CDC recommends an additional primary series mRNA vaccine dose in people with immunocompromise aged ≥12 years²
- Approximately 1.4 million children ages 5-17 years have an immunocompromising condition³
- Safety findings from VAERS and v-safe during administration of >8 million doses of Pfizer-BioNTech: rare reporting of any serious side effects⁴

¹ Embi et al MMWR 5 Nov 2021; ² CDC Interim Clinical Considerations; ³ Patel et al EID 2021; ⁴ Hause et al MMWR 31 Dec 2021
People who have completed a primary series and booster may be better protected against symptomatic infection with Omicron than those without booster. Studies from Israel document the effectiveness of Pfizer-BioNTech booster dose 5 months after primary series against severe illness and death secondary to COVID-19. 188 million (73%) of U.S. adults ages 18 years and older are fully vaccinated; 38% of those have received a booster. 4.74 million (57%) of U.S. adolescents* ages 16-17 years are fully vaccinated with Pfizer-BioNTech COVID-19 vaccine; 6% have received a booster. Rare occurrences of myocarditis in people ages 16 years and older following a booster dose at 5 months occurred at less than half the rate observed following 2nd dose.


* Vaccination data is not available for Idaho
## COVID-19 Vaccine Booster Dose by Primary Series, with Interval

<table>
<thead>
<tr>
<th>Primary series COVID-19 vaccine product*</th>
<th>Age for vaccine booster (years)</th>
<th>Interval between final primary dose and booster dose</th>
<th>COVID-19 vaccine products that may be given as booster dose*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>≥12</td>
<td>≥5 months</td>
<td>Pfizer-BioNTech</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Moderna</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Janssen/J&amp;J</td>
</tr>
<tr>
<td>Moderna</td>
<td>≥18</td>
<td>≥5 months</td>
<td>Pfizer-BioNTech</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Moderna</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Janssen/J&amp;J</td>
</tr>
<tr>
<td>Janssen/J&amp;J</td>
<td>≥18</td>
<td>≥2 months</td>
<td>Pfizer-BioNTech</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Moderna</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Janssen/J&amp;J</td>
</tr>
</tbody>
</table>

*Only Pfizer-BioNTech is authorized as primary series or booster dose for people aged <18 years. For the prevention of COVID-19 in those ages ≥18 years, mRNA vaccines (Pfizer-BioNTech; Moderna) are preferred over the Janssen/J&J COVID-19 vaccine for both primary series and booster doses.
Adolescents ages 12–17 years should receive a booster dose of Pfizer-BioNTech COVID-19 Vaccine

- Pfizer-BioNTech COVID-19 Vaccine is very effective in adolescents for the primary series; however, may wane over time
- Limited data directly on the impact of boosters in adolescent population
- No new safety signals or concerns identified after review of three U.S. safety monitoring systems
- In current Omicron surge, prevention of infection may have larger benefits that are difficult to measure (e.g., population-level protection, school attendance)
# Newest Formulation of Pfizer-BioNTech COVID-19 Vaccine

<table>
<thead>
<tr>
<th>Purple cap</th>
<th>Gray cap</th>
<th>Orange cap</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age indications</strong></td>
<td>12 years and older</td>
<td>12 years and older</td>
</tr>
</tbody>
</table>

## Prep and Administration

<table>
<thead>
<tr>
<th>Prep and Administration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Doses per vial</strong></td>
<td>6</td>
</tr>
<tr>
<td><strong>Dose volume</strong></td>
<td>0.3 mL</td>
</tr>
<tr>
<td><strong>Amount of diluent needed per vial</strong></td>
<td>1.8 mL</td>
</tr>
</tbody>
</table>

## Storage

<table>
<thead>
<tr>
<th>Storage</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ultra-cold freezer</strong></td>
<td>-90°C to -60°C (-130°F to -76°F)</td>
</tr>
<tr>
<td><strong>Freezer</strong></td>
<td>-25°C to -15°C (-13°F to 5°F)</td>
</tr>
<tr>
<td><strong>Refrigerator</strong></td>
<td>2°C to 8°C (36°F to 46°F)</td>
</tr>
<tr>
<td><strong>After first puncture</strong></td>
<td>Discard after 6 hours</td>
</tr>
</tbody>
</table>
Latest Updates to Mask Recommendations
CDC Mask Recommendations

- CDC recommends a layered approach to help slow the spread of COVID-19.
- Masks are a critical part of the layered approach:
  - Wear a mask with the best fit, protection, and comfort for you
  - In areas of substantial or high community transmission, wear a well-fitting mask indoors in public, regardless of your vaccination status.
- Any mask is better than no mask.
  - Take steps to improve how your mask protects you.
- Masks should not be worn by children under the age of 2 or anyone who would be unable to remove the mask without assistance.
Choosing a mask or respirator

- Masks and respirators are effective at reducing spread of COVID-19, when worn consistently and correctly
  - Some masks and respirators offer more protection than others
  - Some may be harder to wear consistently than others
- Wear a well-fitted mask or respirator correctly that is comfortable for you and that provides good protection
- Get the latest information about masks and respirators at CDC’s website
Alternative Masks for Special Situations

Clear masks or cloth masks with a clear plastic panel are an alternative type of mask that may be helpful when interacting with certain groups of people, such as:

- People who are deaf or hard of hearing
- Young children or students learning to read
- Students learning a new language
- People with disabilities
- People who need to see the proper shape of the mouth for making appropriate vowel sounds

The FDA cleared for marketing a transparent medical mask. These transparent medical masks should be reserved for use by healthcare workers and patients who require them.
Overview of New Options Available to States

State Flexibilities to Determine Financial Eligibility for Individuals in Need of HCBS

CMCS All-State Call
February 22, 2022
• This presentation provides information on state authority to target less restrictive financial methodologies to Medicaid applicants and beneficiaries in need of home and community-based services (HCBS).

• This authority gives states an additional tool to use in efforts to “rebalance” their Medicaid coverage of long-term services and supports (LTSS) from institutional to community-based care.

• Recent CMS State Medicaid Director letter “State Flexibilities to Determine Financial Eligibility for Individuals in Need of Home and Community-Based Services” (SMD #21-004, December 7, 2021) provides implementation guidance.
Basics of section 1902(r)(2)-based disregard authority

- Section 1902(r)(2)(A) of the Social Security Act (the Act) directs that states use financial methodologies that are no more restrictive, and which may be less restrictive, than those applied under the most closely-related cash assistance program (e.g., SSI-based methodologies).

Reminder: Disregards may not be applied in MAGI-based eligibility determinations.

- “Less restrictive” methodologies typically involve disregarding a certain amount or type of income or resources.

  For example:
  - $100 in monthly unearned income
  - An amount of income above an income eligibility threshold (e.g., countable income between 100 percent and 150 percent of the federal poverty level)
  - Census Bureau income
  - $5,000 in countable resources
  - A second vehicle

- Federal regulations require that such less restrictive methodologies be comparable for all individuals in an eligibility group – i.e., a disregard made available to any individual in a group must be made available to all. 42 C.F.R. § 435.601(d)(4)
Section 3(b) of the Sustaining Excellence in Medicaid Act of 2019 (Pub. L. 116-39) authorizes states to target disregards at individuals who need or are receiving HCBS without having to also apply the disregard to individuals who need or are receiving institutional services.

This means that states may target disregards at individuals seeking eligibility in the special HCBS waiver-related eligibility group (described at 42 C.F.R. § 435.217) or at individuals who need HCBS authorized under section 1915(c), (i), or (k), or under section 1115 of the Act but are seeking eligibility under another eligibility group.

CMS State Medicaid Director letter “State Flexibilities to Determine Financial Eligibility for Individuals in Need of Home and Community-Based Services” (SMD #21-004, December 7, 2021) provides implementation guidance.
The authority enacted in 2019 permits a state to target a less restrictive methodology at only individuals within an eligibility group who are in need of HCBS. For example:

• A state may target a disregard exclusively at individuals in an eligibility group who need 1915(c), (i), or (k) services without applying the disregard to other individuals in the group

• A state that offers 1915(i) and (k) services under its state plan could target a disregard at individuals who need 1915(i) services

• A state that operates more than one 1915(c) waiver could target a disregard at individuals who meet the coverage criteria for one particular waiver

• A state may target a disregard exclusively to individuals eligible in the group described at 42 C.F.R. §435.217
Vaccine Toolkit and Section 9817 Updates
Questions