Federal Retail Pharmacy Program Updates

Vaccine program updates

New bivalent vaccine booster may be available as early as Labor Day

Both Pfizer and Moderna are planning on submitting data for review and possible approval of a bivalent, omicron-adapted mRNA COVID-19 vaccine. Currently, the plan is to provide a bivalent booster dose to those eligible (completed their primary series).

- When data is first submitted to FDA by **Pfizer**, it will be for the use of the bivalent vaccines for **adult through adolescent boosters (12+) ONLY**.
- When data is first submitted to FDA by Moderna, it will be for use as an **Adult Booster (18+) ONLY**. (There is a possibility they could submit data for 12+.)
    - This means monovalent mRNA vaccine will still be needed at some volume for primary series at the launch of the updated vaccine.
    - While there will likely be enough vaccine for open eligibility, CDC would like to ensure that vulnerable populations (LTC-settings, immunocompromised, 65+) are generally prioritized for your planning.
    - In the most accelerated timeline scenario, there is a possibility some doses could ship over Labor Day weekend. Otherwise, plan for September-October.

CLARIFIED PACK INFORMATION:
The new bivalent vaccines will have the same storage and handling parameters as the original vaccine products:
Pfizer-BioNTech COVID-19 Vaccines

- Ultra-cold freezer storage (-90°C to -60°C) until expiry
- NO FREEZER STORAGE
- Refrigerate (2°C to 8°C) up to 10 weeks without puncturing

Moderna COVID-19 Vaccines

- NO ULTRA-COLD FREEZER STORAGE
- Freezer storage (-25°C to -15°C) until expiry
- Refrigerate (2°C to 8°C) up to 30 days without puncturing

Pfizer-BioNTech bivalent COVID-19 vaccine is expected to be packaged in 6-dose vials in cartons of 10 vials each (60 doses total), with a minimum order quantity of 300 doses.

Moderna bivalent vaccine will be packaged in 5-dose vials in cartons of 10 vials each (50 doses total), with a minimum order quantity of 100 doses.

Once punctured, each vial must be used within 12 hours. Similar to existing Moderna and Pfizer-BioNTech (gray cap) products, vials must be discarded ≤12 hours after the first puncture. Ancillary supplies will be provided, including a variety of 1-inch and 1.5-inch needles and syringes. An ancillary opt-out continues to be available for all non-diluent kits.

Vaccination Cards

Bottom line guidance about CDC vaccination cards; when a vaccination record card is full:

1. Complete a new card for the patient
2. Staple both cards together
3. Encourage the patient to photograph both cards in case they become separated
4. Bring both cards to future vaccination appointments

Janssen vaccine reminder

Please check expirations dates on any Janssen vaccine inventory you have on hand. Much of the Janssen vaccine in the field is dated AUG expiry due to the last shelf-life extension. More recent likely have expiration dates into the fall and there is still a small quantity of vaccine that will expire in DEC/JAN. Expired vaccines should be reported as waste.

V-Safe reminder

The CDC has updated V-Safe. Please remind your patients about this important resource. Click here for V-safe print resources.

Oral antivirals program updates

Evusheld

The U.S. Food and Drug Administration has issued an EUA for the emergency use of the unapproved product EVUSHELD (tixagevimab co-packaged with cilgavimab), SARS-CoV-2 spike protein-directed attachment inhibitor, for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARSCoV-2 and
- Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination or
- For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

EVUSHELD may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which EVUSHELD belongs (i.e., antinfectives).

EVUSHELD has been authorized by FDA for the emergency use described above. EVUSHELD is not FDA-approved for any use, including use for pre-exposure prophylaxis of COVID-19.

- Please place allocation requests through the ABCOrder portal
- **Evusheld should be administered and reported as two courses**
- Reporting on inventory and administrations is mandatory, as it is for all therapeutic products (minimum twice per week)
- Pharmacists **cannot** prescribe Evusheld

Resources

- EUA letter
- FAQ for healthcare providers
- Fact Sheet for patients, parents, and caregivers

Therapeutics allocation requests available via ABC Order

Pharmacies participating in the FRPTP may now request COVID-19 therapeutics allocation through the ABC Order COVID portal, similar to how COVID19 vaccines are requested. Email requests for therapeutics shipments will no longer be accepted. If you do not request therapeutics allocation through the ABC Order COVID portal, therapeutics inventory will not be shipped to your pharmacy. Allocation requests placed

before 12pm ET Wednesdays will be delivered to your pharmacy early the following week. Orders submitted after 12pm on Wednesdays won't be processed until the next cycle.

Resources

Updated Implementation and Allocation Guides

- Therapeutics FAQ
- Therapeutics implementation guide
- Vaccine implementation guide
- Vaccine allocation guide

New to the oral antivirals program? Download these resources!

- Implementation Guide
- FAQ

COVID-19 Treatment Marketing Materials

Let your patients know that you have COVID-19 treatments available at your pharmacy with new print and digital marketing materials. Visit the "Coronavirus" library in Brand Central Station and SOCi to access the materials.

Surveys, reporting, reminders

Survey: Partnering with Long-Term Care facilities

The CDC has asked if any pharmacies participating in FRPP are currently partnering with any Long-Term Care Facilities, or if they would be able to. Please take this brief survey.

Are you interested in dispensing COVID-19 antiviral therapies?

If you are currently enrolled in the vaccine program and are interested in participating in the antiviral program, please email the Elevate Enrollments team at elevateenrollments@amerisourcebergen.com.

At this time, only pharmacies enrolled in the vaccine program may participate in the antiviral program.

Questions? Continue to work with your Business Coach or Sales Executive or send questions to COVIDVaccines@AmerisourceBergen.com. Please include your pharmacy name and NCPDP on all communications. This information will help us expedite our response to you.

AmerisourceBergen