A Vaccine Is Coming. Are You Prepared?

Every day there is new information – and speculation – on progress toward a COVID-19 vaccine. And each day, new questions emerge. How are trials going? Which manufacturers will apply for emergency authorization? How much will it cost? With persistent uncertainty, the best path is to educate yourself and take steps to be prepared.

We're all looking forward to a fresh start after this very difficult year. But as 2021 approaches, employers face the daunting task of budgeting for the anticipated uptick in their vaccination costs. To support these efforts, Rx Solutions is working with our pharmacy benefit management (PBM) partners to compile guidance regarding vaccine developments and bring as much clarity as possible to this evolving situation.

FUNDING IN PLACE

The federal government has provided over $10 billion to leading vaccine manufacturers to expedite the development of an FDA-approved vaccine and support the mass production over 300 million doses. Creating a viable vaccine in such a short time is a monumental task, but the necessary financial support is in place to accelerate results.

CARES ACT PROVISIONS

The Coronavirus Aid, Relief, and Economic Securities Act (CARES Act) includes provisions to ensure rapid uptake of any COVID-19 vaccine. A vaccine will be considered a "preventive health service" and must be covered without cost sharing for Medicare and Medicaid plans. COVID-19 vaccines will be covered under Medicare Part D and therefore, all Part D plans will be required to cover the vaccine. Additionally, the CARES Act created a federal fund to provide the vaccine free of charge to people who do not have health insurance.

COLLABORATION WITH INSURERS

The US government is working with commercial health insurers to provide COVID-19 vaccines without copays, but details of these discussions have not been made public. PBMs anticipate that the federal government will cover vaccine costs due to its large-scale purchase commitments, but insurers will likely assume responsibility for reimbursing healthcare providers for the cost of vaccine administration.

ADMINISTRATION GUIDANCE

Vaccines are typically administered in physicians' offices, so they are primarily covered by medical benefits. We expect COVID-19 vaccines to be handled in a similar manner once they become available. However, with so many individuals needing vaccination, additional channels may be required to meet the demand as quickly as possible and this may alter how vaccinations are covered.

On September 3, 2020, the US Department of Health and Human Services issued guidance authorizing state-licensed pharmacists to order and administer COVID-19 vaccinations to persons ages three or older. Three States (New York, New Jersey and New Hampshire) have already updated their vaccine administration regulations to include COVID-19 vaccines for administration by pharmacists.

VACCINE CANDIDATES

According to the World Health Organization, 34 COVID-19 vaccine candidates are currently in clinical development worldwide and another 145 vaccine candidates are in pre-clinical (non-human) study. While this area is evolving rapidly, it is important for plan sponsors to monitor developments, understand the current state of vaccine development and begin considering their options for managing COVID-19 vaccines if one or more should become available in the coming months.

Of the many options in play, there are currently six vaccine candidates that have the greatest potential to reach the US marketplace within the next 12 months (see table here). Viability and availability of these candidates are heavily dependent on the results of Phase 3 clinical trials.

DEVELOPMENT OVERSIGHT

Public concerns regarding vaccine safety remain, including questions as to whether the rush to develop a viable vaccine could undermine the scientific process. The FDA has taken several steps to assure the public of its commitment to scientific rigor, integrity and transparency in their review of vaccine candidates.

In June, the FDA issued clear guidance to drug manufacturers regarding its expectations for a clinical trial structure and related scientific data, which it will require in its evaluation processes. In addition, a Data and Safety Monitoring Board, comprised of fully independent research experts, is reviewing emerging data from trials as they progress and has authority to pause or halt trials in the event of serious adverse events. Lastly, prior to final review of all vaccines, the agency will convene its Vaccines and Related Biological Products Advisory Committee (VRBPAC) as trial data is aggregated.

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