FDA approvals and expedited pathways used - new molecular entities (NMEs)

Published: Oct 1, 2020 - **Products & Programs** / Pharmacy

We review the activities of the Food and Drug Administration (FDA)'s approval of drugs and biologics on a regular basis to understand the potential effects for both our providers and members.

The FDA approves new drugs/biologics using various pathways of approval. Recent studies on the effectiveness of drugs/biologics going through these different FDA pathways illustrates the importance of clinicians being aware of the clinical data behind a drug or biologic approval in making informed decisions.

Here is a list of the approval pathways the FDA uses for drugs/biologics:

- **Standard review** – The standard review process follows well-established paths to help ensure drugs/biologics are safe and effective when they reach the public. From concept to approval and beyond, FDA performs these steps: reviews research data and information about drugs and biologics before they become available to the public; watches for problems once drugs and biologics are available to the public; monitors drug/biologic information and advertising; and protects drug/biologic quality. *Click this link to learn more about the standard review process.*

- **Fast track** – Fast track is a process designed to facilitate the development, and expedite the review of drugs/biologics to treat serious conditions and fill an unmet medical need. *Click this link to learn more about the fast track process.*

Article Attachments

New 2020 FDA molecular entities approvals.pdf
application/pdf - 120.15 KB

- **Priority review** – A priority review designation means FDA's goal is to take action on an application within 6 months. *Click this link to learn more about the priority review process.*
- **Breakthrough therapy** – A process designed to expedite the development and review of drugs/biologics that may demonstrate substantial improvement over available therapy. *Click this link to learn more about the breakthrough therapy process.*
- **Orphan review** – Orphan review is the evaluation and development of drugs/biologics that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. *Click this link to learn more about the orphan review process.*
- **Accelerated approval** – These regulations allowed drugs/biologics for serious conditions that filled an unmet medical need to be approved based on a surrogate endpoint. *Click this link to learn more about the accelerated approval process.*

New molecular entities approvals: January - August 2020

Certain drugs/biologics are classified as new molecular entities (NMEs) for purposes of FDA review. Many of these products contain active ingredients that have not been approved by FDA previously, either as a single ingredient drug or as part of a combination product; these products frequently provide important new therapies for patients.

We review the FDA-approved NMEs on a regular basis. To help facilitate the decision-making process, we have attached to this article a list of NMEs approved from January to August 2020 along with the FDA approval pathway utilized.

Source: www.fda.gov

650-1020-PN-NE

URL: https://providernews.anthem.com/maine/article/fda-approvals-and-expedited-pathways-used-new-molecular-entities-nmes-4

Featured In:
October 2020 Anthem Connecticut Provider News, October 2020 Anthem Maine Provider News