FDA approvals and expedited pathways used - New Molecular Entities (NMEs)

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Anthem reviews 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.

Article Attachments

FDA-approved NMEs 10.20.pdf
application/pdf - 461.77 KB

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 make sure 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. *To learn more about the Standard Review process, click here.*

- **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. *To learn more about the Fast Track process, click here.*
- **Priority Review** – A Priority Review designation means FDA's goal is to take action on an application within 6 months. *To*

learn more about the Priority Review process, click here.

- **Breakthrough Therapy** – A process designed to expedite the development and review of drugs/biologics which may demonstrate substantial improvement over available therapy. *To learn more about the Breakthrough Therapy process, click here.*
- **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. *To learn more about the Orphan Review process, click here.*
- **Accelerated Approval** – These regulations allowed drugs/biologics for serious conditions that filled an unmet medical need to be approved based on a surrogate endpoint. *To learn more about the Accelerated Approval process, click here.*

New Molecular Entities approvals: Jan–Aug 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.

Anthem reviews the FDA-approved NMEs on a regular basis. To facilitate the decision-making process, we are providing the attached list of NMEs approved from January to August 2020 along with the FDA approval pathway utilized.

Open attached PDF titled "**FDA-approved NMEs 10.20".**

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