FDA approvals and expedited pathways used: new molecular entities

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Anthem Blue Cross and Blue Shield (Anthem) reviews the activities of the 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 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, go **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, go **here**.
- **Priority Review:** A Priority Review designation means FDA's goal is to take action on an application within six months. To learn more about the Priority Review process, go **here**.

Article Attachments

New molecular entities approvals. January to August 2020.pdf
application/pdf - 264.27 KB

- **Breakthrough Therapy:** A process designed to expedite the development and review of drugs/biologics that 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**.

Please open the attached PDF titled "**New molecular entities approvals. January to August 2020.pdf**" to view new molecular entities approvals from January to August 2020.

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