

Accelerated Drug Approval



A National Survey of Neurology Clinicians



**Clinical
Neurological
Society of America**

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Introduction

The FDA's Accelerated Approval Program can cut years off the time it takes for a new, safe and effective drug to become available to patients. The process offers hope for patients who face serious diseases with limited treatment options.

Accelerated Approval is one of four FDA programs designed to speed up drug approval. The others are Fast Track, Priority Review and Breakthrough Therapy. Each program offers a slightly different pathway to ensure that novel medications that meet FDA requirements can get to patients faster.

Whatever the pathway, expediting FDA approval of novel, safe and effective medications helps address a variety of serious unmet medical needs. These can range from neurological conditions with high population disease burden to rare illnesses that impact a relatively small number of patients but have no existing treatment.

Through recent national polling of 254 neurologists, neurology nurse practitioners and neurology physician assistants, the Clinical Neurological Society of America gauged awareness, attitudes and experiences with drugs that have been approved through the FDA's Accelerated Approval Program.

Findings revealed that most neurology clinicians generally understand the pathway and the benefits that it can offer. However, others are unfamiliar with the program, which may lead to potential misunderstandings about the efficacy and safety of drugs delivered through the program.

Awareness

Neurology clinicians consider themselves generally knowledgeable about the accelerated approval pathway, though they have less confidence in the average health care provider's understanding of it.

78%

Report knowing "some" or "a lot" about the accelerated approval process



39%

Say the average health care provider has that same level of understanding

When asked about the requirements for a drug to undergo accelerated approval, most neurology clinicians knew that using a surrogate endpoint to predict a clinical benefit is a unique requirement for the process:

83%

Know that companies must conduct studies predicting a clinical benefit based on a surrogate endpoint

12%

Are "unsure" about this requirement

5%

Believe that this is not a requirement for accelerated approval



Neurology clinicians' understanding of accelerated approval tends to be largely conceptual, however. Most can name only a handful of drugs that have been through the process. When asked about specific drugs, either in neurology or in any other medical specialty, that have been through the accelerated approval pathway:



54%

Say they could name between one and three drugs

18%

Say they could name four or more drugs



Experience

About one-fourth of polled neurology clinicians aren't sure whether or not they've ever prescribed an accelerated approval drug.





When asked if they had prescribed their patients medications that were approved via accelerated approval, neurology clinicians responded:



- 37%** Yes
- 36%** No
- 27%** Unsure

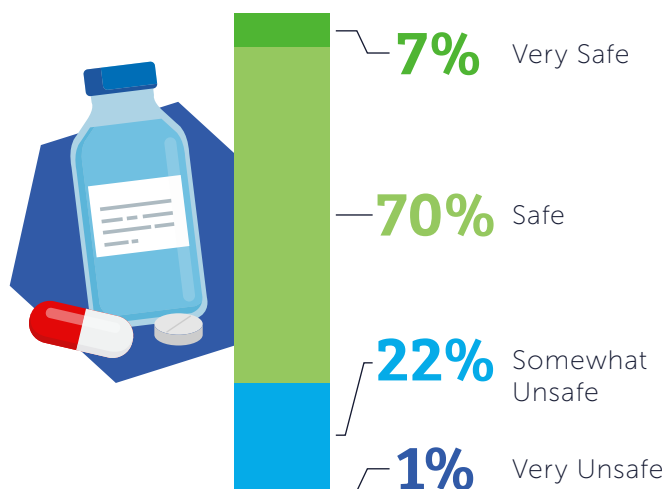
Trusted Information Sources

What sources of information do neurology clinicians trust for information about accelerated approval?

-  **74%** FDA
-  **71%** Scientific Journals
-  **53%** Medical Societies
-  **3%** Mainstream News Outlets

Safety & Confidence

A majority of neurology clinicians consider accelerated approval drugs to be safe.



Despite their relative confidence, however, some clinicians mistakenly think that accelerated approval drugs are held to lower standards for safety and efficacy. When asked whether medications in an accelerated approval pathway must meet the same standard of safety and efficacy required of medications subjected to traditional approval, neurology clinicians replied:



65%
Agree

24%
Disagree

11%
Are unsure

Some survey participants also question the FDA's success at balancing safety and timeliness. When asked whether the FDA does a good job balancing approval timeliness with drug safety and efficacy for the accelerated approval pathway, neurology clinicians:



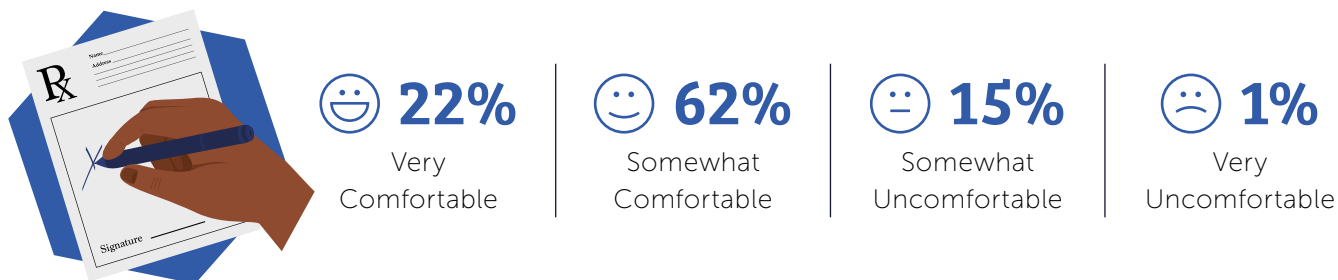
75%
Agreed or Strongly Agreed



25%
Disagreed or Strongly Disagreed

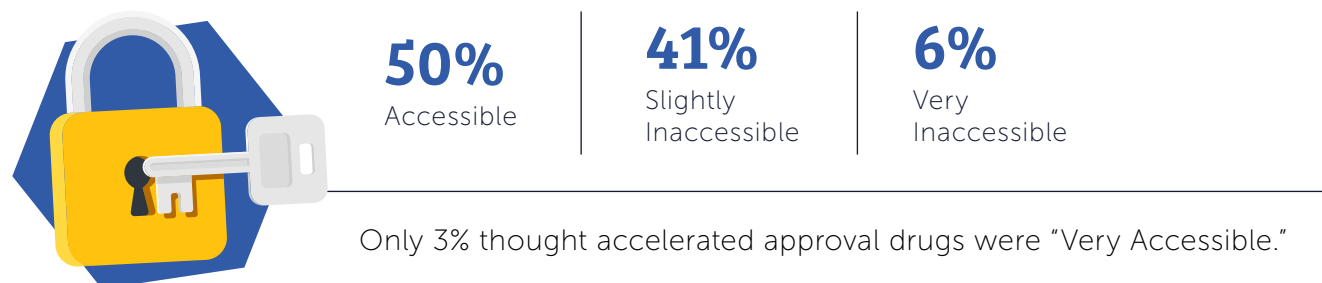
Prescribing & Accessibility

The vast majority of neurology clinicians are comfortable prescribing accelerated approval drugs, despite any misconceptions about safety:



Access issues remain a concern, however.

About half of the neurology clinicians surveyed consider accelerated approval drugs inaccessible to patients.



Access to accelerated approval drugs is decidedly worse, respondents reported, compared to access for drugs approved through the traditional process.

Surveyed neurology clinicians said that accelerated approval drugs, compared to traditionally approved drugs, are:



Coverage & Barriers

Respondents cited insurance barriers, such as prior authorization and step therapy, as the most common challenges to patient access.

Limited insurance coverage and high out-of-pocket costs are also considered a challenge, along with misinformation and a lack of education, which can make patients uncomfortable with using these drugs.

Surveyed neurology clinicians reported:

"Patient education material is sometimes scarce."

"Consumer pushback. Fear of side effects that are anticipated."

"Insurance coverage issues are an important factor."

When asked whether **commercial**, **Medicaid** and **Medicare** plans generally cover accelerated approval drugs, respondents had mixed perceptions.

Strongly Disagree Disagree Agree Strongly Agree



Commercial Coverage

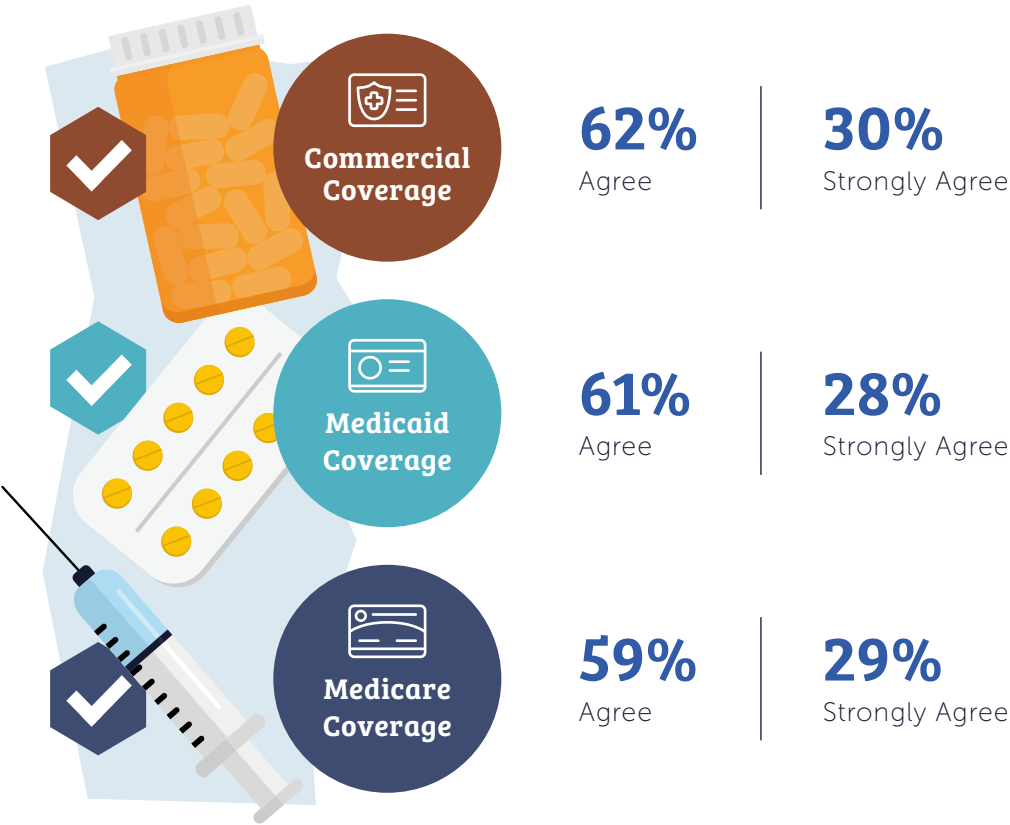


Medicaid Coverage



Medicare Coverage

Surveyed neurology providers agree overwhelmingly, however, that these drugs should be covered by:



Moving Forward

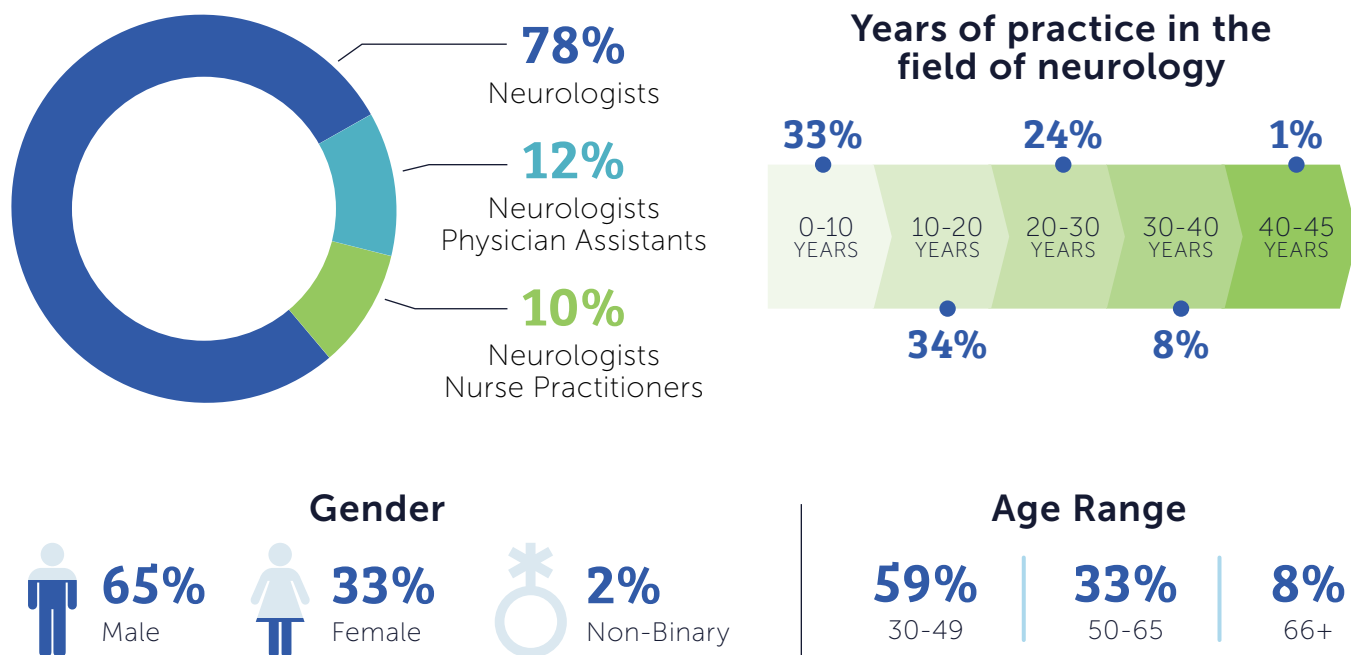
The FDA's Accelerated Approval Program offers an important pathway to filling unmet medical needs. People living with neurological conditions are among the many patients who stand to benefit.

As the Clinical Neurology Society of America's national survey found, several obstacles may hinder accelerated approval drugs from benefitting patients to their full potential. These include coverage barriers and misconceptions that may lead some clinicians to underestimate the efficacy and overestimate the risk of accelerated approval medications.

Moving forward, maximizing the potential value of the accelerated approval program may require heightened collaboration, greater attention to questions of access, and increased education for patients and clinicians.

About the Data

The sample for this nationwide survey was 254 respondents working in the clinical neurology field:



CNSA's Clinical Awareness Initiative

The Clinical Neurological Society of America has nearly 50 years of experience bringing together leading experts and clinical neurologists for educational programming. The society's clinical awareness initiatives focus on increasing awareness about important topics within the practice of health care and the policy and regulatory environment that shapes that care.

CNSA recognizes the project's advisors for the accelerated approval clinical awareness initiative.



**David
Charles, MD**
Chair



**David J.
Houghton,
MD, MPH**



**Nina
Riggins,
MD, PhD**



**Robert E.
Shapiro,
MD, PhD**



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The Clinical Neurological Society of America was created in 1974 as an organization for neurologists practicing in clinical and academic settings. Since then, the society has grown into a nationwide organization of clinicians with a mission to improve clinical practice and patient care through education.



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