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New Technology Add-On Payment in 2026: Positioning Your Drug, Device, or Diagnostic for Success

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Participant audio and video are disabled for the duration of the webinar.

Ask your questions using the Zoom Q&A feature. Questions will be addressed at the end of the presentation.

Copies of presentation materials and a recording of today's webinar will be available within ~72 business hours on www.healthmanagement.com/insights

Agenda

- NTAP Overview
- Qualifying for NTAP
  - Newness
  - Substantial Clinical Improvement
  - Cost Threshold
- Program Experience to Date
- Recent Trends and Potential Policy Changes
- Lessons Learned and Tips for Engaging With CMS

NTAP Overview

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Why NTAP Exists

- NTAP was enacted by Congress as part of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 to provide expanded access to new, high-cost medical services and technologies under the **inpatient** hospital payment system
- Congress created NTAP in recognition of the inability of the diagnosis-related group (DRG) system to fully account for the cost of a new, high-cost technology without several years of retrospective data collection
- In implementing the new provision, the Centers for Medicare & Medicaid Services (CMS) promulgated regulations specifying **three** criteria for granting an NTAP:

01

Newness

02

Cost Threshold

03

Substantial Clinical Improvement

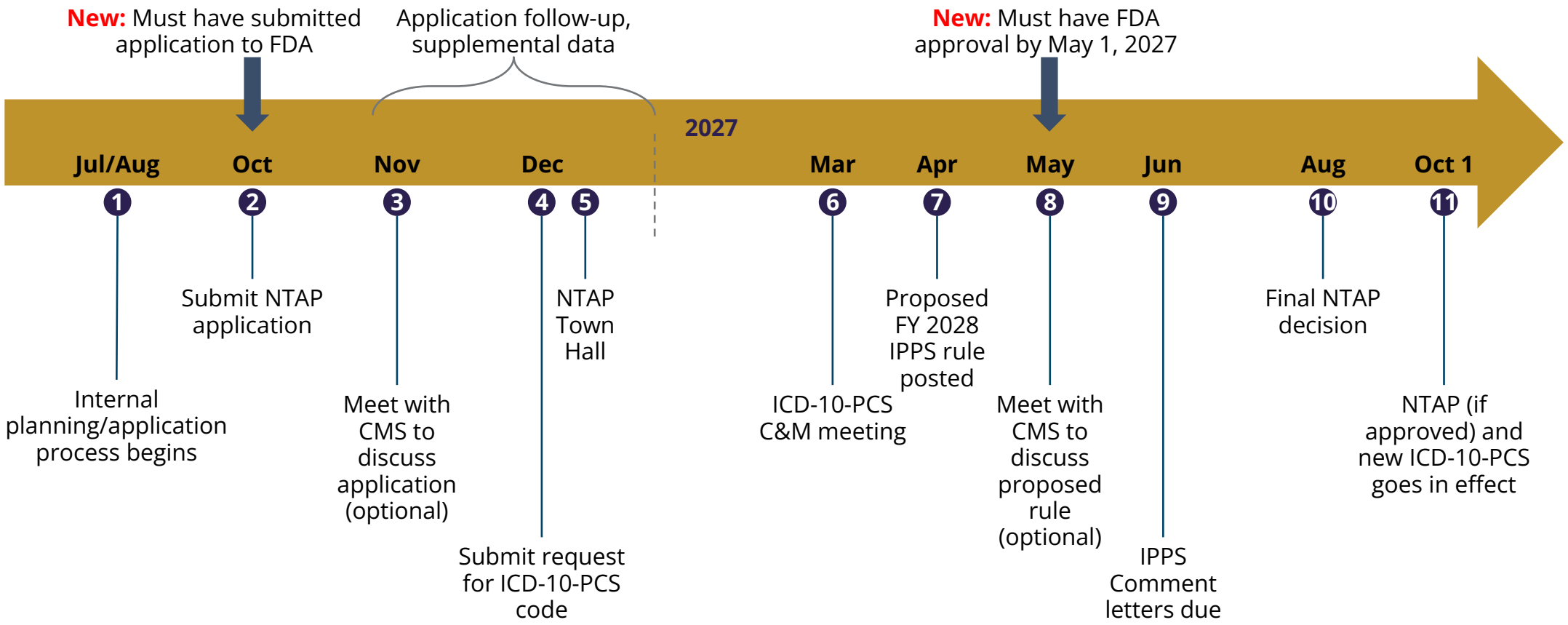
How NTAP Works

- Hospitals get an extra payment, in addition to the regular DRG payment, when they use an NTAP product. This payment is not designed to make the hospital whole.
- NTAP payment is the lesser of
  - 65% of the cost of the product or
  - 65% of the cost of the case above the regular DRG payment
- Effective for the FY 2021 NTAP cycle, hospital add-on payments for QIDPs and LPADs are calculated as follows:
  - Additional payment is capped at the lesser of 75% of the estimated cost of the qualifying technology; or
  - 75% of the cost of the case above the regular DRG payment
- NTAP payments are available for the 2-3 year period after FDA approval/market entry

Is NTAP Right for a New Technology?

- Are you developing or have recently launched a biopharmaceutical product, medical device, diagnostic, or other innovative medical technology?
- Do you expect your product to have inpatient hospital usage?
- Is your product distinct from existing technologies used to treat the same disease and/or patient population?
- Do you have clinical data supporting your product's medical claims?
- Will the costs of the technology be significant compared to the current MS-DRG payment?

NTAP Application Timeline



Note: Sample process for FY 2028 only. Meetings with CMS are not required or guaranteed. Deadlines subject to change.

Qualifying for NTAP

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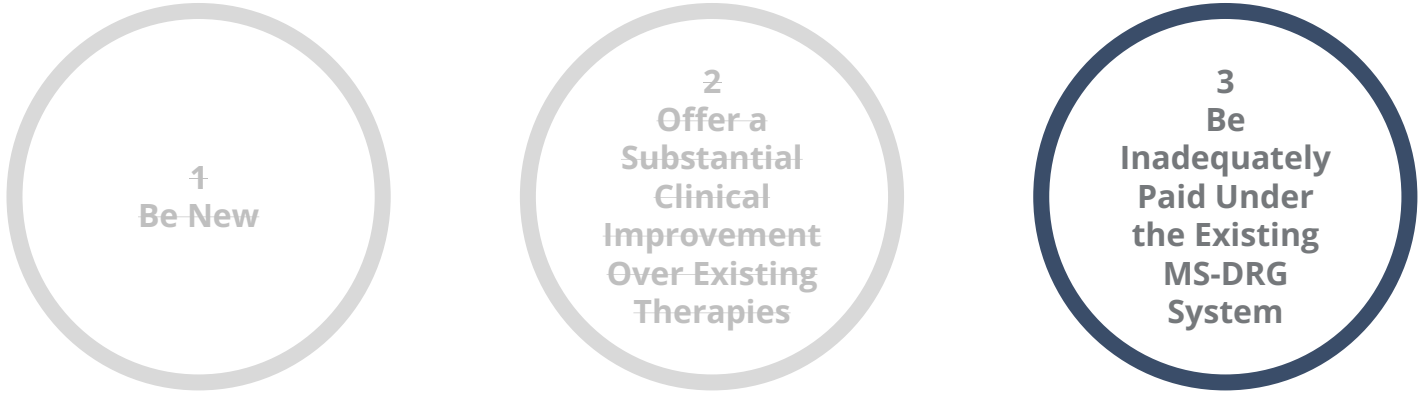
The Three Criteria (by pathway)

Traditional pathway: for most medical technologies

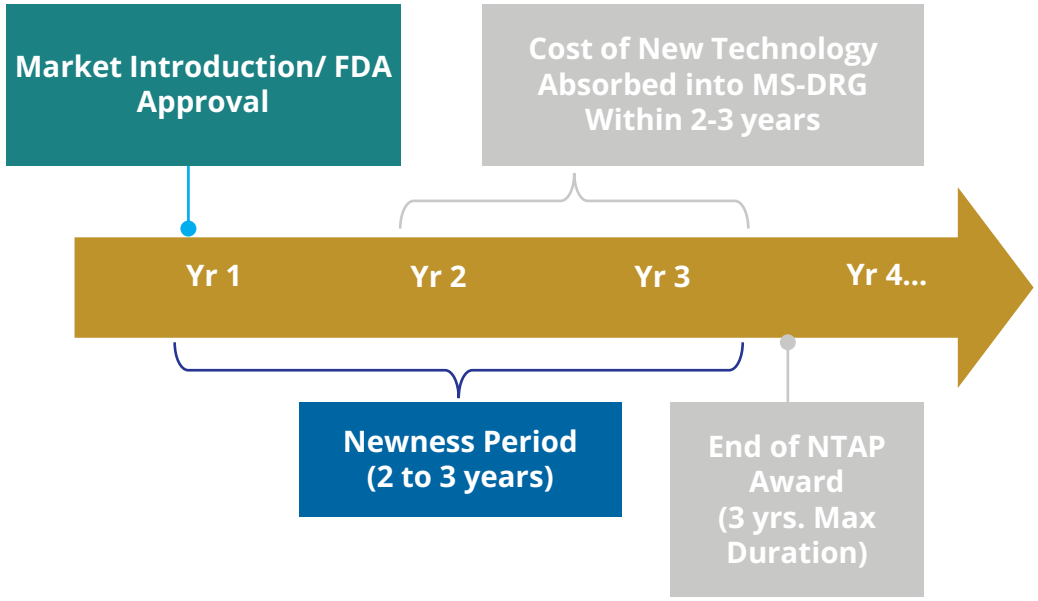
Alternative pathway: for breakthrough devices, QIDPs and LPADs



*Note: If CMS finalizes its policy in the FY 2027 IPPS Proposed Rule, the alternative pathway will no longer apply.

1. Newness Criterion

- Technologies are considered "new" for two to three years, at which time data reflecting the cost of the technology should be available to determine
  MS-DRG payments
- Note on new indications for existing drugs/biologicals:
  - CMS has not ruled out considering a drug with a new indication as "new"
  - New indication must not be "substantially similar" to prior indication



To be considered for FY 2028, technologies must have a complete and active FDA marketing authorization request by application deadline and FDA approval by May 1, 2027

1. Newness Criterion (cont'd.)

- CMS has determined that a technology is considered "new" until claims data reflecting the use of that technology become available
  - CMS typically uses FDA approval as the market entry date for a "new" technology, and not the issuance of an ICD-10 procedure code
- Must show it is not "substantially similar" to existing technologies. CMS considers:
  1. Whether product uses same/similar mechanism of action to achieve therapeutic outcome
  2. Whether product is assigned to same/different MS-DRG
  3. Whether a new use of the technology involves treatment of the same or similar type of disease and the same or similar patient population

Must not meet all three

1. Newness Criterion (cont'd.)

- **Example from FY 2024 Rulemaking on Substantial Similarity:**
  - CMS considers two NTAP applications for Genmab's EPKINKLY™ and Genentech's COLUMVI™, both bispecific antibodies for the treatment of R/R LBCL
  - In the Final Rule, CMS determines both products are substantially similar and thus evaluates both technologies as one application
  - CMS will use the earliest marketing availability date as the beginning of the newness period for both products
  - CMS also uses a weighted average of the cost of both products, rather than separate payment amounts

2. Substantial Clinical Improvement

- Use must significantly improve clinical outcomes for a patient population as compared to currently available treatments
- Clinical data must be specific or generalizable to Medicare beneficiary age group
- Prevalence in Medicare population not a consideration
- CMS has outlined these qualifications in regulations

Examples of Outcomes That May Demonstrate "Clinical Improvement"
Reduced mortality rate with use of the technology
Reduced rate of procedure- or technology-specific complications
Decreased rate of subsequent diagnostic or therapeutic interventions (e.g., due to reduced rate of recurrence of the disease)
Decreased number of future hospitalizations or physician visits
Increased resolution of the disease process because of the use of the technology
Decreased pain, bleeding, or other quantifiable symptom
Reduced recovery time

2. Substantial Clinical Improvement (cont'd.)

1. The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
2. The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
3. Use of the technology significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:

    - Reduced mortality rate with use of the device.
    - Reduced rate of device-related complications.
    - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
    - Decreased number of future hospitalizations or physician visits.
    - More rapid beneficial resolution of the disease process treatment because of the use of the device.
    - Decreased pain, bleeding, or other quantifiable symptom.
    - Reduced recovery time.

CMS Has Clearly Stated That "*Demonstration of a Substantial Clinical Improvement Over Existing Technologies Is Not Necessarily Inherent in the FDA's Regulatory Requirement for the Technology*"

3. Cost

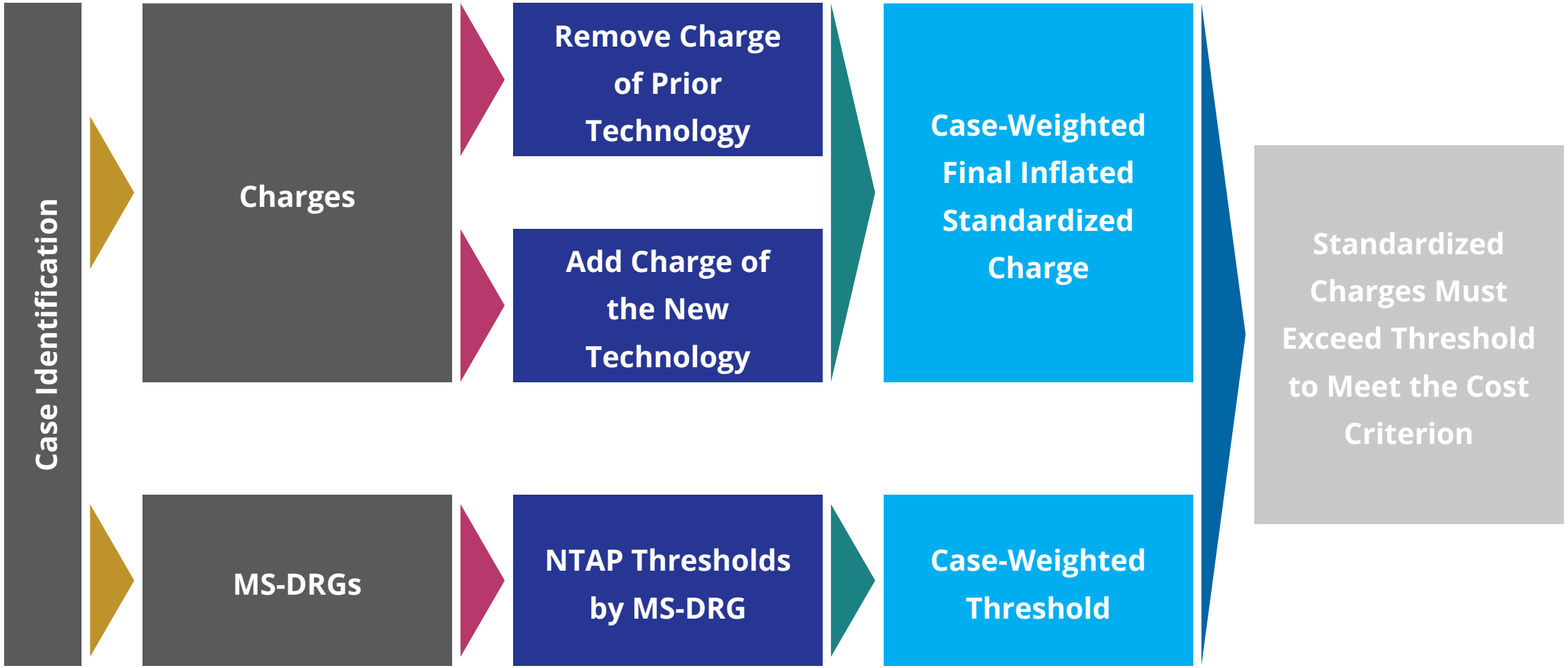
- **Step One:** Identify hospital claims from the past where the product would have been used had it been available
  - Limited to only the information on administrative claims, such as DRG assignment, diagnosis codes and procedure codes
- **Step Two:** Reprice those claims as if the product had been used
  - Add in cost of new technology and anything else that will occur along with the new technology that isn't already included
  - Subtract out the costs of anything that will not occur when the new technology is used
- **Step Three:** Compare the average charges on those claims to a CMS-calculated threshold

If you exceed the threshold, you've met the cost criterion!

Quirks of the Cost Criterion

- **CMS is focused on the hospitalization only**
  - Costs occurring outside the hospital stay (such as outpatient or physician care) are not included
- **Extremely strong preference for the analysis to be done with CMS claims data used to create DRG payments**
  - Other internal cost information can supplement the analysis
- **The cost criterion is based on hospital charges – which tend to be marked up from their costs**
  - How this markup is estimated could become increasingly important as costs for "transformative therapies" rise
- **Given the proprietary nature of technology pricing, some applicants use placeholders based on the minimum amount necessary to show the cost criterion is met**
  - In some cases, the types of patients being treated with the technology are more expensive, meaning that claims for those patients meet the threshold even without including technology cost

Standard Cost Analysis Methodology



Program Experience to Date

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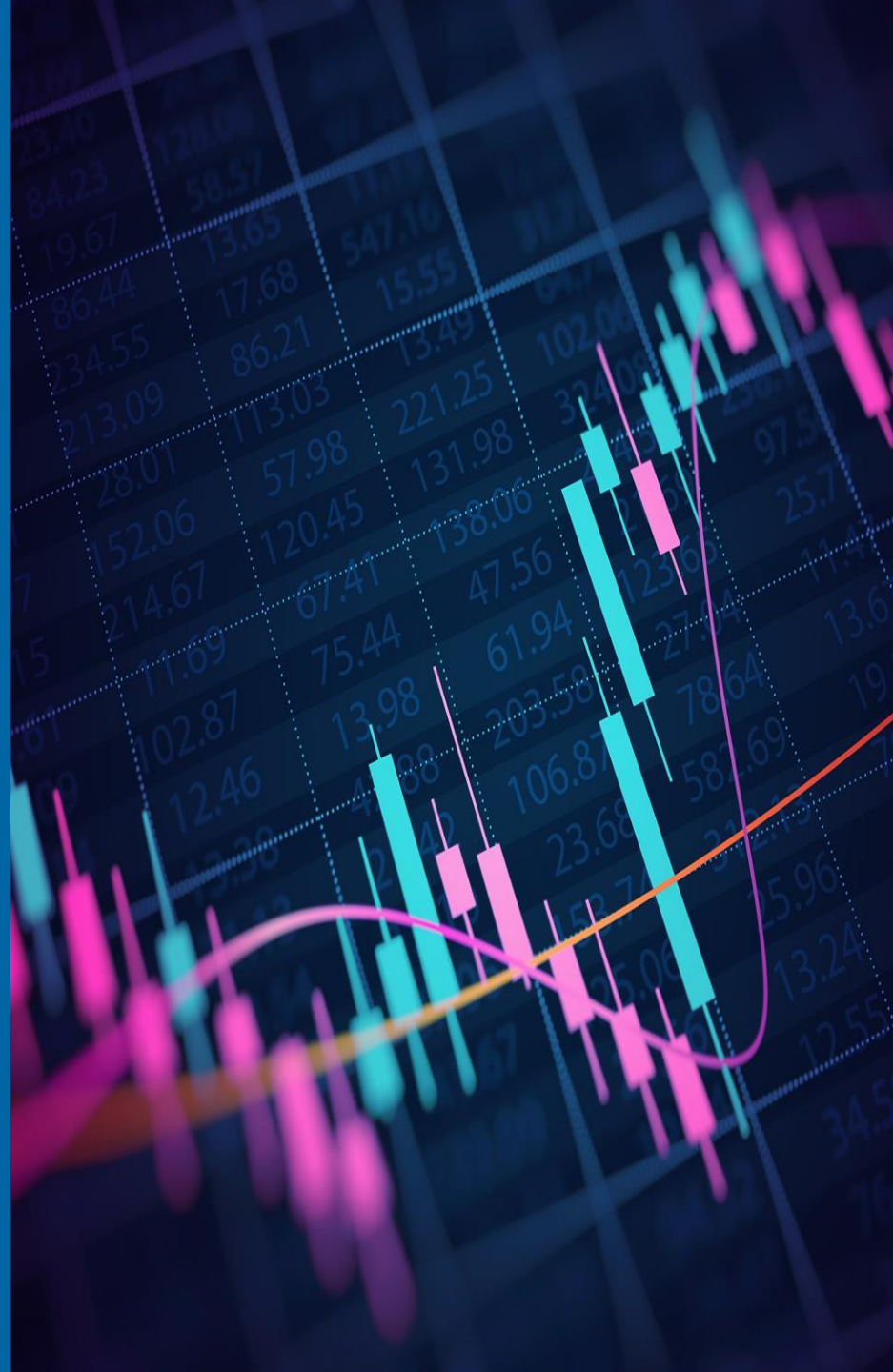
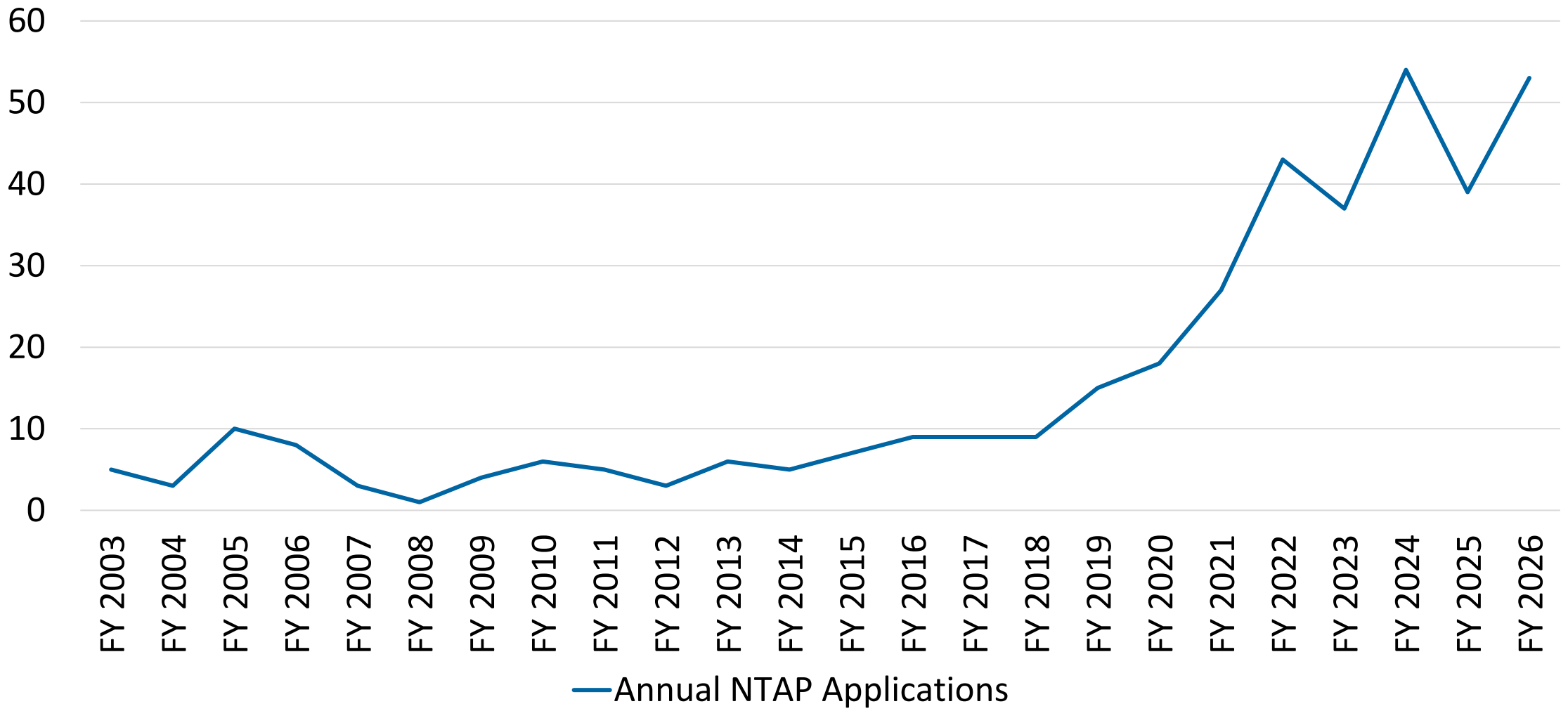


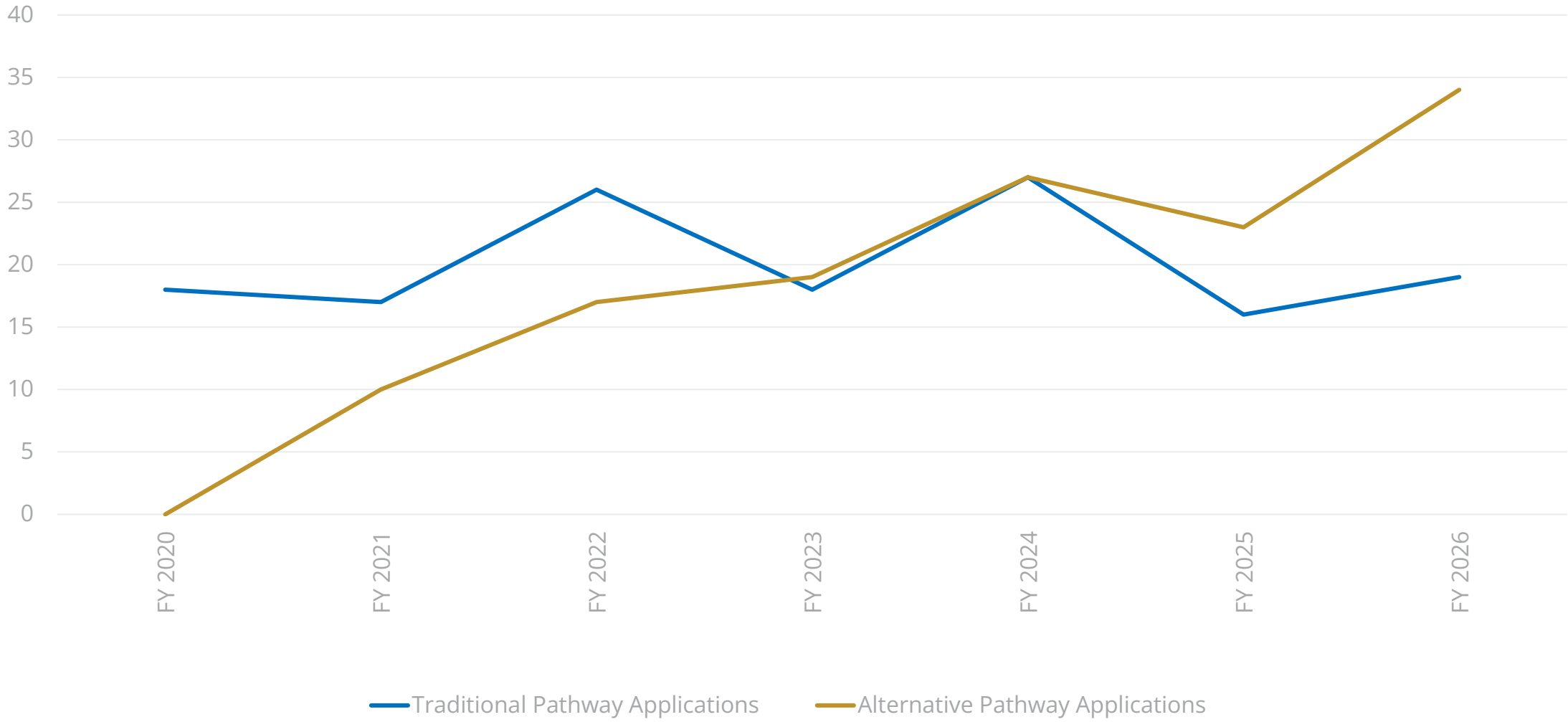
Increasing Number of NTAPs

Year	Applied	Approved	Withdrawn	Denied	Denied Due to Not Meeting the Following Criteria			
					FDA Approval	Newness	Cost Threshold	Substantial Clinical Improvement
FY 2003	5	1	1	3		2	1	
FY 2004	3	1		2		1	1	
FY 2005	10	2		8		5		3
FY 2006	8	2		6	1	2		3
FY 2007	3	1	1	1				1
FY 2008	1			1				1
FY 2009	4	1		3	3			
FY 2010	6	1	4	1				1
FY 2011	5	1	2	2				2
FY 2012	3		1	2		1		1
FY 2013	6	3	2	1	1			
FY 2014	5	3	2	0				
FY 2015	7	3	2	2				2
FY 2016	9	2	2	5	1	2		2
FY 2017	9	5	2	2		1		1
FY 2018	9	3	5	1	1			
FY 2019	15	7	7	1	1			
FY 2020	18	9	4	5	1			4
FY 2021	27	15	3	9	4			5
FY 2022	43	17	12	13	4	2	1	7
FY 2023	37	10	23	4	3			1
FY 2024	54	22	26	6	3	1		2
FY 2025	39	15	10	14	8	1		5
FY 2026	53	27	10	16	8	4		4
Total	**379**	**151**	**119**	**108**	**39**	**22**	**3**	**45**

Increasing Number of NTAPs (cont'd.)

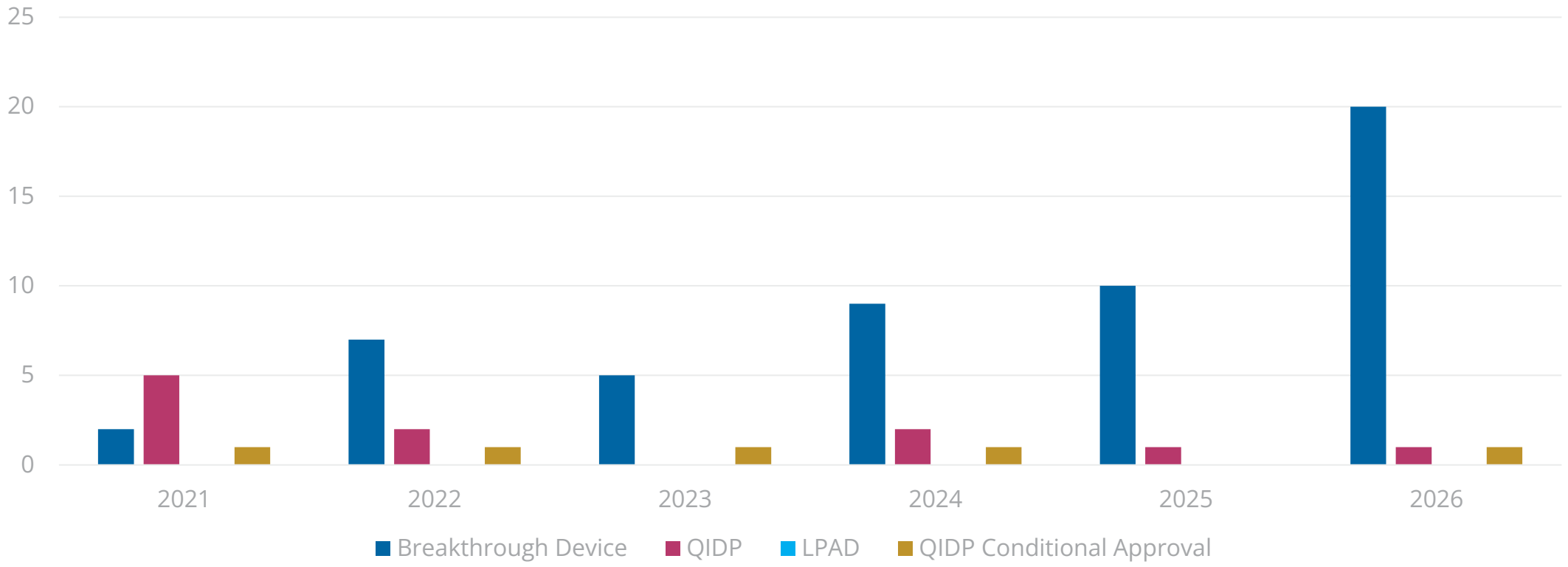


But Growth Has Also Been Driven by Alternative Pathway Applications

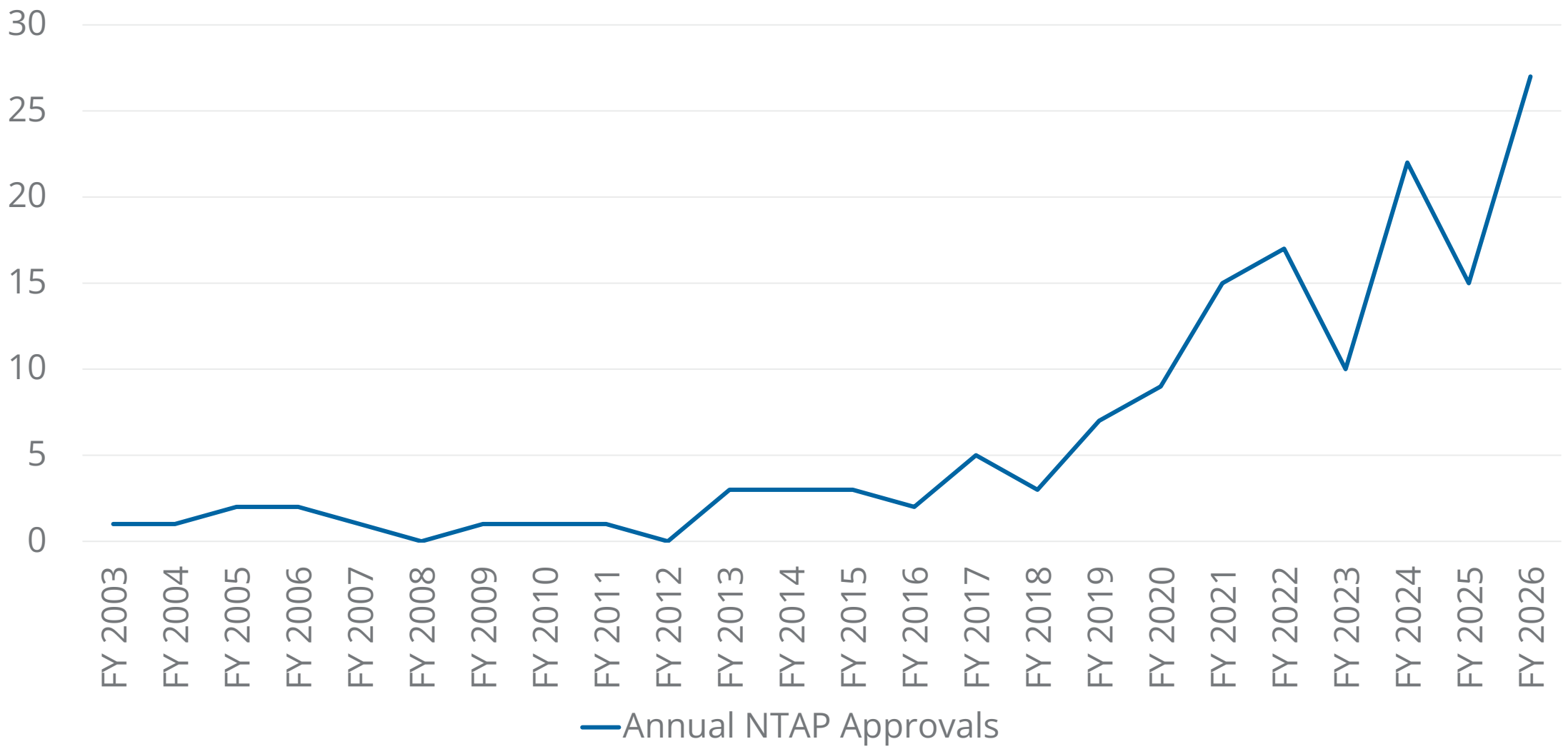


Approvals under Alternative Pathway

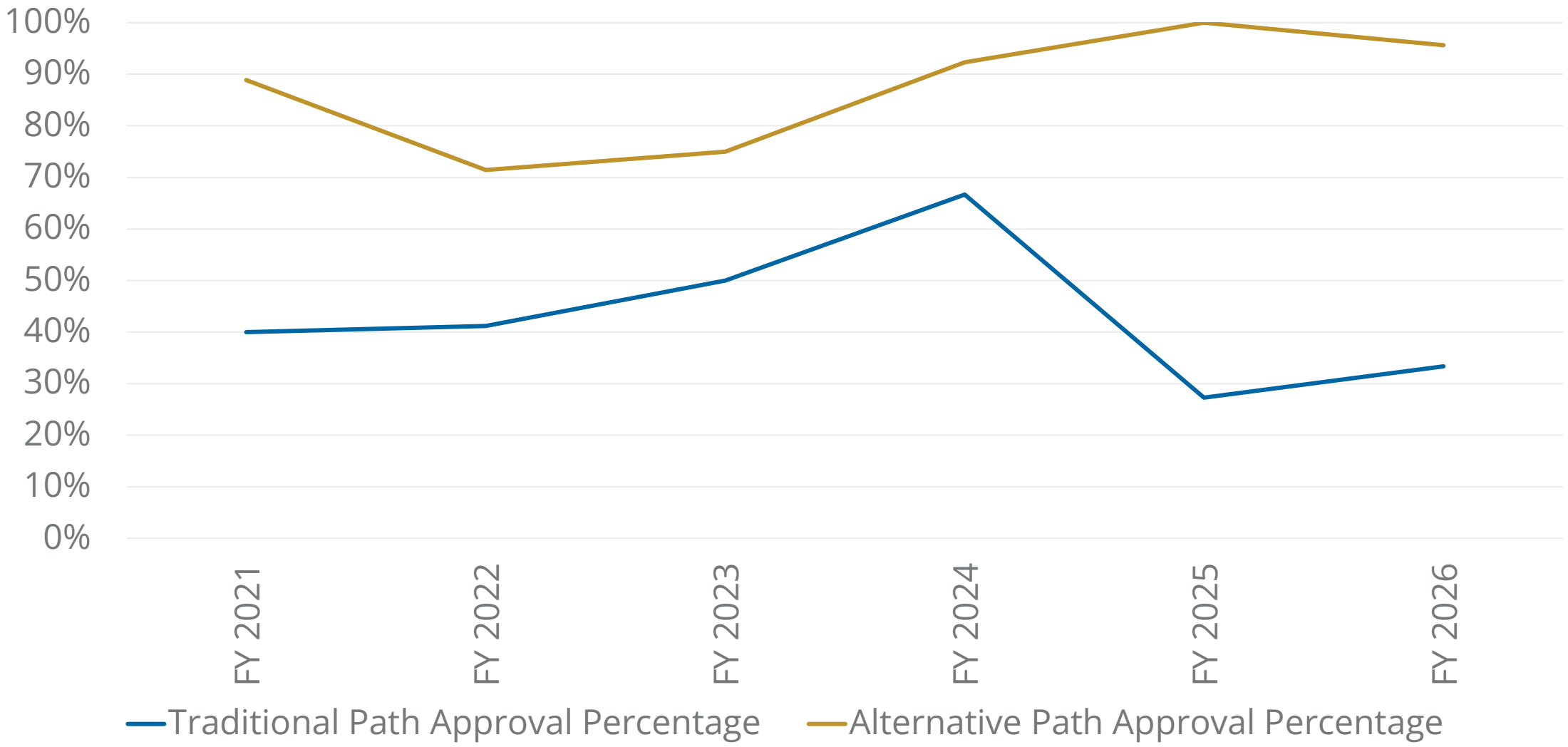
FY 2021-2026



Historical NTAP Approvals

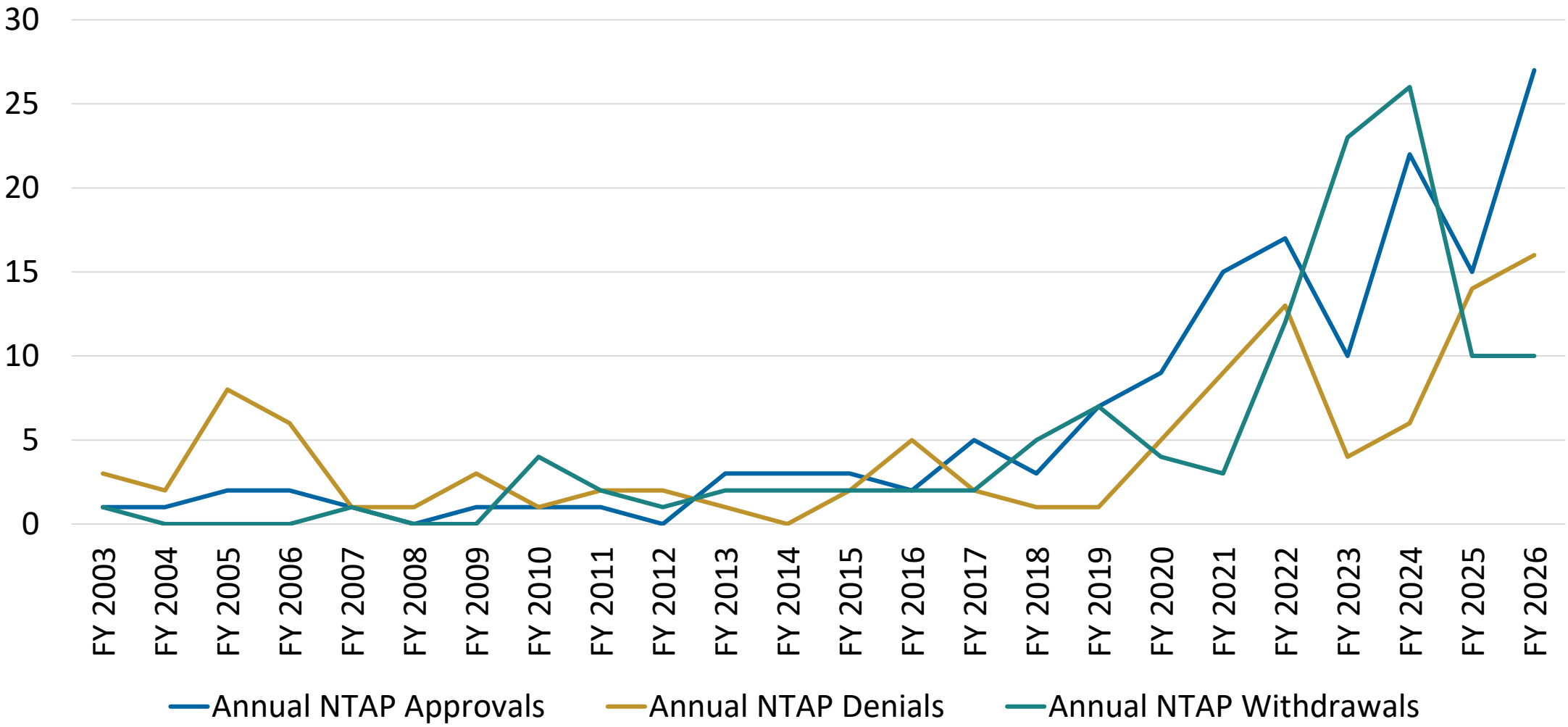


A Tale of Two Pathways: Approval Rates Diverge

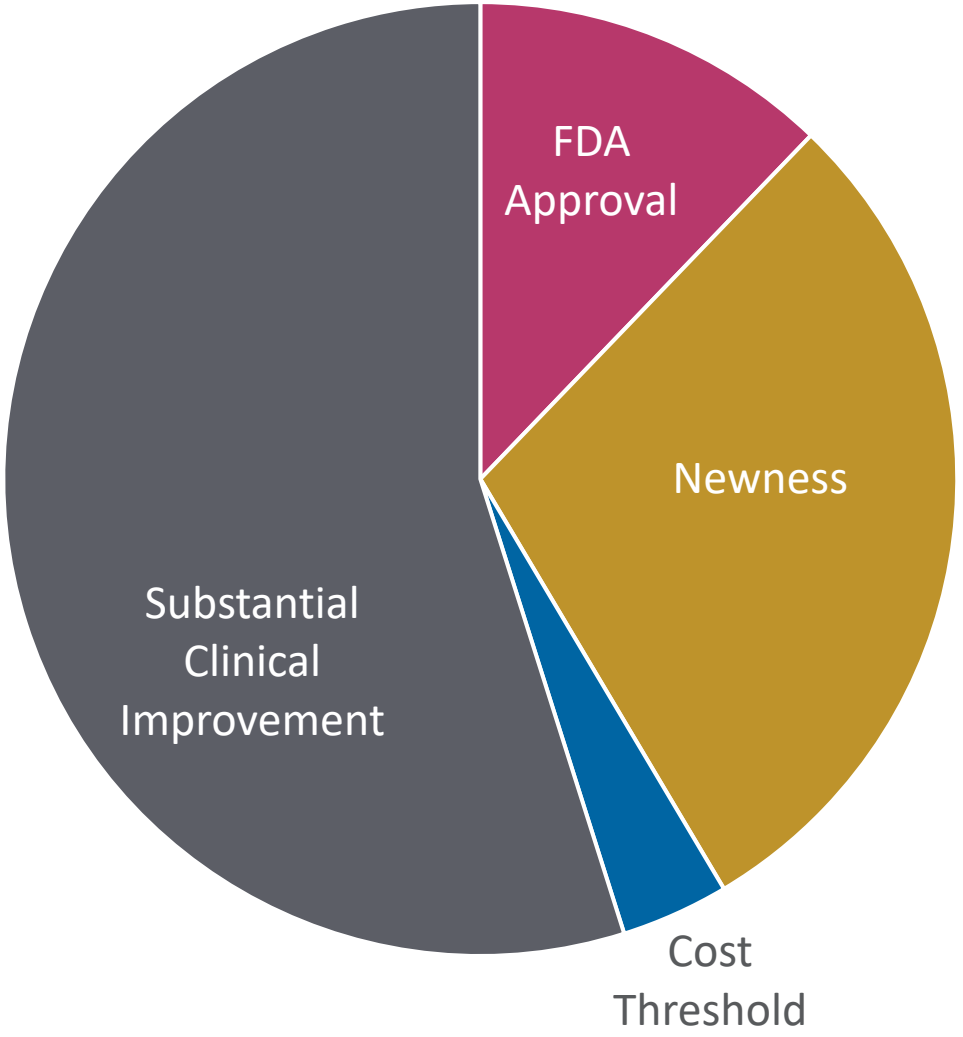


*Numerator is based on total number of approvals, including conditional approvals, for each pathway in a given fiscal year. Denominator is the number of applications minus those withdrawn prior to the proposed rule discussion (typically due to inability to meet FDA approval deadline).

Historic NTAP Activity



Historical Reasons for Denial (Traditional Pathway)



Recent Trends and Potential Policy Changes

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Recent Policy Changes to NTAP

CMS has recently adopted policy changes that modify the NTAP program to achieve its policy goals:

FY 2020: Established alternative pathway to qualify for NTAP that waives the newness and substantial clinical improvement criteria

FY 2020: Increased NTAP payment amount from 50% to 65%; and for QIDPs and LPADs to 75%

FY 2021: Conditional approval for QIDP and LPAD products for NTAP so that payment begins on the quarter following FDA marketing authorization

FY 2024: CMS begins requiring FDA market authorization by application deadline and approval by May 1st

FY 2025: Increased NTAP payment amount from 65% to 75% for gene therapies treating Sickle Cell Disease (SCD).

Potential Future NTAP Changes

- **CMS considers changes to the NTAP process through the annual IPPS rulemaking process**
- **In recent years, stakeholders have requested numerous changes:**
  - Increase add on payment to 75% (or greater)
  - "Uniform add-on payment" for all cases
  - Extend alternate pathway to breakthrough drugs and biologicals
  - Make NTAP applicable for 3 calendar years
- **In the FY 2027 Proposed Rule, CMS is proposing two changes:**
  - CMS is proposing to **repeal the "alternative pathway" for breakthrough medical devices, QIDPs, and LPADs**
  - CMS is proposing to limit recognition of commercial availability delays (for the purposes of a product's newness start date) to the period prior to the effective date of an NTAP for the applicable fiscal year

Lessons Learned and Tips for Engaging With CMS

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Five Tips for a Successful NTAP

Plan

Begin planning well in advance of the application deadline, which is typically early to mid-October; consider conducting a preliminary feasibility assessment

Assess

Assess internal resources (medical, regulatory) and identify key outside experts (to assist with drafting application, engaging with CMS, and running the cost threshold analysis

Engage

Plan to actively engage in public forums and during comment periods

Support

Build support for your application by identifying and engaging with key KOLs to publicly support your application

Educate

Following assignment of NTAP, work with hospitals and physicians to educate on the NTAP and appropriate billing

Limitations of NTAP

Some common feedback from manufacturers and providers on NTAPs:

- **Add-on amount is not transparent to hospitals at time of treatment**
  - CMS makes determination following submission of claims with hospital charges
  - Payment amount is not uniform (lesser of standard)
  - NTAP payment goes to the hospital and not particular charge center where utilized
  - NTAP payment depends on hospital charging practices
- **Temporary for two to three years**
  - Under current rules many NTAPs only receive two years of add-on payment
  - Following NTAP expiration, MS-DRG payment may not reflect true cost of product
- **Only limited to Medicare FFS**
  - Not followed by Medicare Advantage, Medicaid
  - Private payers
- **For products used in numerous MS-DRGs, NTAP education may be more challenging**

Center for Medicare "New Tech" Team

- **Key differences between FDA and CMS review process**
- **NTAPs are reviewed by the Center for Medicare**
  - CMS established in 2020 a dedicated Technology Coding and Pricing Group (TCPG)
  - Division of New Technology
- **Each applicant will be assigned a "Navigator" for the application process**
- **Reviewers are a mix of policy experts and medical advisers**
- **Medical advisers may not be expert in your particular medical specialty**
  - Provide clear explanations of scientific and medical content
  - Use CMS language and formats as much as possible
- **CMS makes available "New Technology Liaisons" who may be contacted at MedicareInnovation@cms.hhs.gov**

Engaging With CMS on Your Application

✓ DO

- Engage early with CMS to solicit feedback on your application
- Provide supplemental filings of new clinical evidence, data, publications, and FDA approvals
- Anticipate “critical” feedback during the proposed rule process
- Identify internal or external champions (ideally from Med Affairs or a KOL) to be the public face of your engagement. Medical advisers may not be expert in your particular medical specialty

✘ DON’T

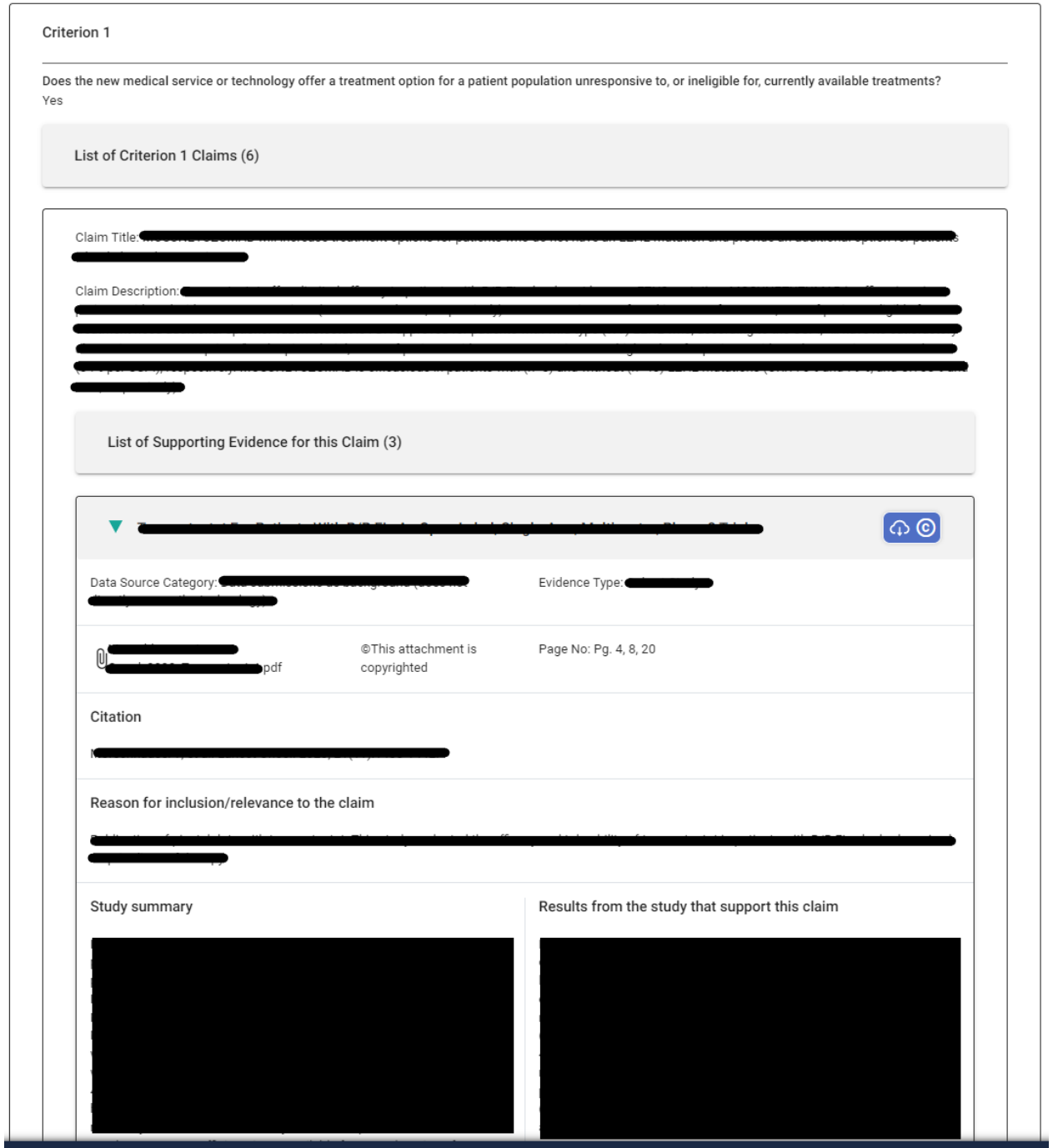
- Rely solely on your application to make your arguments – your strategy should include in-person engagement and agency staff and participation in public meetings
- Fail to mark any proprietary or non-public information as trade secret exempt from FOIA
- Assume CMS understands your technology and data
- Be discouraged by preliminary review in the IPPS Proposed rule (public comment period after the proposed rule is the most critical time to respond to agency concerns and questions)

Tips for Navigating MEARIS

MEARIS™
Medicare Electronic Application Request Information System™

- **Build your application using the MEARIS text fields and word-count restrictions**
- **Utilize attachments/appendices where necessary to provide additional information that won't fit within word counts and text-only boxes**
- **Give yourself plenty of time to navigate an imperfect and sometimes glitchy system**
- **Understand the structure/requirements for the revamped "Substantial Clinical Improvement" section which is now built around**
  - Criterion;
  - Claims;
  - Claims descriptions; and
  - Supporting evidence

MEARIS SCI Example



Criterion 1

Does the new medical service or technology offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments?
Yes

List of Criterion 1 Claims (6)

Claim Title: [redacted]

Claim Description: [redacted]

List of Supporting Evidence for this Claim (3)

[redacted]

Data Source Category: [redacted]

Evidence Type: [redacted]

[redacted].pdf

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Page No: Pg. 4, 8, 20

Citation

[redacted]

Reason for inclusion/relevance to the claim

[redacted]

Study summary

[redacted]

Results from the study that support this claim

[redacted]

Q&A

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