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Boston Scientific AGENT™ Drug-Coated Balloon NTAP Application Eligibility

March 26, 2024

Boston Scientific Attendees

- Jenny Levinson, Vice President, Global Health Economics and Market Access
- Dan Krause, Vice President, Regulatory Affairs
- Steve LaPierre, Senior Director of Government Affairs
- Chris Timmerman, Senior Director of Government Affairs
- Whitney Craig, Senior Director of Government Affairs
- Ta-Yuan Ho, Director, Health Economics and Market Access, Coronary Therapies
- Yajuan Lu, Director, Health Economics and Market Access

Review of Issue and Requested Action

- Issue
  - The AGENT™ Drug-Coated Balloon FY 2025 NTAP submission meets all NTAP application requirements, but CMS declined to accept the application for review.
  - CMS stated that we did not meet a new requirement to document FDA's determination that the AGENT™ FDA application was sufficiently complete to permit a substantive review.
  - BSC submitted the documentation specified in regulation, along with further documentation requested by CMS, **all of which was dated before the October 17, 2023, FY 2025 NTAP application deadline.**
- Request
  - Find CMS has wrongfully interpreted Section 42 CFR §412.87.
  - Determine AGENT™ Drug-Coated Balloon NTAP application shall be reviewed in the FY2025 IPPS Proposed Rule.

Interpretation of 42 CFR §412.87

- For FY 2025, CMS added a new requirement to submit documentation to prove that the FDA application is "complete and active."
  - The intent as stated by CMS is to reduce the burden of reviewing applications that are unlikely to receive FDA approval in time for the NTAP.
- The language under 42 CFR §412.87 and other CMS guidance specify documentation of either FDA **acceptance or filing** fulfills the new requirements
  - With respect to NTAP applications that have not yet received FDA marketing authorization, 42 CFR §412.87 states the following documentation must be provided with the application:
    - (2) The new medical service or technology is the subject of a complete and active FDA marketing authorization request and documentation of FDA **acceptance or filing** of the request is provided to CMS. (emphasis added)
  - FY2024 IPPS Final Rule:
    - "…the agency will only accept new technology add-on payment applications once FDA has received all of the information to determine whether it will **accept** (such as in the case of a 510k application or De Novo Classification request) **or file** (such as in the case of a PMA, NDA, or BLA) the application, as demonstrated by the acceptance/filing letter that is already provided by FDA to indicate that FDA has determined that the application is sufficiently complete to allow for substantive review by FDA." [emphasis added]
  - MEARIS NTAP Submission Platform:
    - "Upload FDA **acceptance or filing** letter" [emphasis added]

Boston Scientific AGENT™ NTAP Application Meets All Requirements of 42 CFR §412.87.

Issue Details

- In accordance with 42 CFR §412.87, we submitted the **FDA Acceptance Letter** as part of our NTAP application on October 16, 2023.
- CMS requested the Filing Letter on October 25, 2023, and we provided it on October 27, 2023.
- On November 13, 2023, CMS informed us that AGENT™ is ineligible for NTAP consideration in FY 2025, "because documentation of FDA acceptance or filing of the marketing authorization request…was not provided to CMS at the time of the new technology add-on payment application submission."
- In subsequent communications (12/6/2023 and 3/11/2024 emails), CMS incorrectly stated that the filing letter was dated October 27, 2024, after the October 17, 2024, deadline.
  - The Filing Letter states the filing date is **October 5, 2023**.
  - The official FDA Approval Order shows **October 5, 2023,** as the filing date, per FDA's official record (Premarket Approval (PMA) (fda.gov)).
  - FDA lead reviewer provided email affirmation that ***"the official FDA filing date for P230035 was October 5, 2023."***

FY2025 IPPS Final Rule: The purpose of the document requirement is to demonstrate that "FDA has determined that the application is sufficiently complete to allow for substantive review by FDA". (*58955 Fed. Reg. 88, Aug. 2023)*

Timeline of AGENT™ NTAP Submission

Required Materials	Submission Deadline	Boston Scientific Submission
Complete NTAP application in MEARIS	10/17/23	✓ Submitted Oct. 16, 2023
Acceptance or filing letter	10/17/23	✓ Acceptance Letter submitted as part of application on Oct. 16, 2023
CMS requested Filing Letter on October 25, 2025	N/A	✓ Filing letter submitted Oct. 27, 2023 **Letter notes filing submission date as Oct. 5, 2023**
Nov. 13, 2023, CMS issued ineligibility notification (AGENT™ NTAP deemed ineligible for consideration for FY 2025)		
Feb. 29, 2024, FDA issued full FDA approval for AGENT™ (FDA.gov)		

Implications of Deeming the AGENT™ NTAP Application Ineligible

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Patient Access Implications

- Limited or delayed adoption by facilities that are unable to cover the incremental costs associated with this new technology;
- Limited access for patients who would benefit from this therapeutic option, including those with in-stent restenosis, and many with comorbidities such as diabetes, high cholesterol, high blood pressure and high BMI; and
- Delayed uptake of coronary Drug Coated Balloon therapy in the US, which is already trailing the global market where these devices have been available for ~10 years.

Policy Implications

- Inconsistent with the NTAP policy intent, which is to promote Medicare beneficiary access to innovative technologies.
- Contrary to CMS' strategic pillar to "drive innovation to tackle our health system challenges."

If delayed until the FY 2026 cycle, AGENT™ will have been on the market for 20 months before NTAP is available and will have less than 18 months of NTAP eligibility in total.

Conclusion

Based on this context, we request OMB to:

- Find CMS has wrongfully interpreted Section 42 CFR §412.87.
- Determine AGENT™ Drug-Coated Balloon NTAP application shall be reviewed in the FY2025 IPPS Proposed Rule.

Staff resources required to review the application are minimal because the AGENT™ Drug-Coated Balloon NTAP application was submitted under the alternative pathway for new medical devices that are part of the FDA Breakthrough Devices Program – no clinical review is required.

THANK YOU!