LAW OFFICES OF STEPHENSON ACQUISTO & COLMAN

# Disclaimer — Review of CMS Annual Rulemaking

The following summary and analysis of the Centers for Medicare & Medicaid Services (CMS) annual rulemaking is provided for general informational purposes only. It reflects our review of the rule as published as of the date of this communication and does not constitute legal, compliance, or regulatory advice.

**Proposed rules are not final and are subject to change.** Where this material addresses a proposed rule, the provisions discussed represent CMS's proposals only. A proposed rule does not constitute final agency action, carries no binding effect, and may be modified, withdrawn, or adopted in materially different form following the public comment period. Payment rates, thresholds, effective dates, program requirements, and other terms may change before a final rule is issued. Nothing in this material should be relied upon as a statement of the requirements that will ultimately take effect.

**The rule is subject to individual review, interpretation, and implementation.** Application of the rule depends on each organization's specific facts, operational structure, patient or beneficiary population, and existing compliance posture. This material does not account for those individual circumstances. Each reader and organization is responsible for its own independent review of the rule, for forming its own interpretation of how the rule applies, and for determining the appropriate manner and timing of implementation within its operations.

**No legal advice; no attorney-client relationship.** This material is not a definitive legal interpretation of any CMS rule and should not be construed as legal advice or as a substitute for review of the official rule text published in the Federal Register. Reading or relying on this material does not create an attorney-client relationship.

**Consult qualified counsel.** Given the complexity of CMS rulemaking and the potential for change, readers and organizations — including providers, payers, administrators, and other healthcare stakeholders — should consult qualified legal, compliance, or regulatory counsel for guidance tailored to their specific circumstances before taking or refraining from any action based on the rule.

# CY 2027 OPPS Proposed Rule — Device Pass-Through Payment Applications (§ IV.A)

*These are proposed determinations. CMS seeks public comment on all 13 applications and will make final determinations in the CY 2027 final rule with comment period.* (Medicare OPPS and ASC Payment Systems Proposed Rule § 2)

## 1. The count: 19 received → 13 under consideration

CMS received **19 applications** by the March 2, 2026 quarterly deadline — the last quarterly deadline for inclusion in the CY 2027 proposed rule. **Six applicants subsequently withdrew**, leaving **13 complete applications** that CMS discusses and takes comment on: **10 under the alternative (Breakthrough Device) pathway and 3 under the traditional pathway.** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) The six withdrawn applications are not named or evaluated in the rule. (Medicare OPPS and ASC Payment Systems Proposed Rule § A)

By quarter of receipt: five in Q2 2025, eight in Q3 2025, one in Q4 2025, and five in Q1 2026. **Seven were preliminarily approved during quarterly review**: MY01, RemeOs™ Screw LAG Solid, WiSE® CRT System, SetPoint System, TOUCH® CMC 1 Prosthesis, Esprit™ BTK, and TOPS™ System. (Medicare OPPS and ASC Payment Systems Proposed Rule § A)

**Bottom line on the 13:** CMS proposes to **approve 7 and deny 6.** (Medicare OPPS and ASC Payment Systems Proposed Rule § 2) (For context, 21 device categories currently receive pass-through payment, each eligible for at least 2 but not more than 3 years. (Medicare OPPS and ASC Payment Systems Proposed Rule § A))

## 2. The 13 applications and CMS's proposed determinations

### Alternative (FDA Breakthrough Device) pathway — 10 applications

| # | Device | Applicant | What it is | Proposed determination |
|---|---|---|---|---|
| a | Altius® Direct Electrical Nerve Stimulation System | Neuros® Medical, Inc. | Implantable neuromodulation system delivering high-frequency nerve stimulation for post-amputation pain | **Deny** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) |
| b | Esprit™ BTK Everolimus Eluting Resorbable Scaffold System | Abbott Laboratories | Resorbable drug-eluting scaffold for infrapopliteal lesions in chronic limb-threatening ischemia | **Approve** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) |

| # | Device | Applicant | What it is | Proposed determination |
|---|---|---|---|---|
| c | MY01 Continuous Compartmental Pressure Monitor | MY01 Inc. | Real-time monitor of muscle-compartment pressure to diagnose compartment syndrome | **Approve** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) |
| d | ProSense® Cryoablation System (incl. ProSense ® Cryoprobe) | IceCure™ Medical Ltd. | Liquid-nitrogen cryoablation system for low-risk breast cancer tumors | **Deny** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) |
| e | RemeOs™ Screw LAG Solid | Bioretec, Inc. | Resorbable metal (LAG) bone screw | **Approve** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) |
| f | SetPoint System | SetPoint Medical | Implanted vagus-nerve neuroimmune modulation therapy for rheumatoid arthritis | **Approve** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) |
| g | TIDAL™ Fusion Cage | restor3d | Porous titanium fusion cage used in limb-salvage/bone-restoration procedures | **Deny** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) |
| h | TOPS™ System | Premia Spine, Inc. | Motion-preserving lumbar spinal implant anchored with pedicle screws | **Approve** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) |
| i | TOUCH® CMC 1 Prosthesis | Medartis | Dual-mobility total first carpometacarpal (thumb) joint prosthesis | **Approve** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) |
| j | WiSE® (Wireless Stimulation of the Endocardium) CRT System | EBR Systems, Inc. | Leadless, ultrasound-powered endocardial pacing for cardiac resynchronization therapy | **Approve** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) |

## Traditional pathway — 3 applications (all proposed for denial)

| # | Device | Applicant | What it is | Proposed determination |
|---|---|---|---|---|
| a | EndoForce™ Connector for Endovascular Venous Anastomosis | Phraxis Inc. | Endovascular connector for attaching an arteriovenous graft to a vein in ESRD hemodialysis patients | **Deny** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) |

| # | Device | Applicant | What it is | Proposed determination |
|---|---|---|---|---|
| b | LINK™ External Fixator | Metric Medical Devices, Inc. | Dynamic percutaneous external fixator providing continuous compression for fractures/fusions | **Deny** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) |
| c | Santreva™-ATK Endovascular Revascularization Catheter | AngioSafe®, Inc. | Energy- and wire-free catheter for crossing/revascularizing complex peripheral artery occlusions | **Deny** (Medicare OPPS and ASC Payment Systems Proposed Rule § A) |

**Approvals (7):** Esprit™ BTK, MY01, RemeOs™ Screw LAG Solid, SetPoint System, TOPS™ System, TOUCH® CMC 1 Prosthesis, WiSE® CRT System. In each, CMS agrees the device meets all applicable pass-through criteria at § 419.66. (Medicare OPPS and ASC Payment Systems Proposed Rule § A)

**Denials (6):** Altius®, ProSense®, TIDAL™ (alternative pathway) and EndoForce™, LINK™, Santreva™-ATK (traditional pathway). In each denial, CMS states it is "unable to determine" that the device meets the (new device category) eligibility criteria. (Medicare OPPS and ASC Payment Systems Proposed Rule § A)

*Illustrative cost detail:* For the Esprit™ BTK, the applicant reported a cost of $3,000.00 per scaffold, an average of 3.55 scaffolds per case, and an average cost per case of $10,650; it was preliminarily approved effective April 1, 2026. (Medicare OPPS and ASC Payment Systems Proposed Rule § A)

## 3. The eligibility framework CMS applied

Under section 1833(t)(6) of the Act, pass-through payment targets devices offering substantial clinical improvement where cost could otherwise impede patient access. (Medicare OPPS and ASC Payment Systems Proposed Rule § A) To qualify under § 419.66(b), a device must: have required FDA approval/clearance (or an appropriate exemption) with the application filed **within 3 years** of FDA marketing authorization; be reasonable and necessary under § 1862(a)(1)(A); and be an integral, single-patient device that contacts human tissue and is implanted, inserted, or applied to a wound. (Medicare OPPS and ASC Payment Systems Proposed Rule § A)

To establish a **new device category** under § 419.66(c), the device must not fit an existing category, must satisfy a three-part **cost-significance test** (each threshold keyed to 25%/10% of the applicable APC payment), and must demonstrate **substantial clinical improvement.** (Medicare OPPS and ASC Payment Systems Proposed Rule § A)

**Alternative pathway.** Since CY 2020, a device with an FDA **Breakthrough Device** designation that has received marketing authorization for the designated indication is **not**

evaluated against the substantial-clinical-improvement criterion, but must still meet the other § 419.66 requirements (including cost significance). (Medicare OPPS and ASC Payment Systems Proposed Rule § A) This is why the 10 alternative-pathway applications are analyzed separately from the 3 traditional-pathway ones.

## 4. A change on the horizon: proposed repeal of the alternative pathway

CMS flags that, in the **FY 2027 IPPS/LTCH PPS proposed rule**, it has proposed to **repeal the alternative pathway** for both new technology add-on payments and OPPS device pass-through. If finalized, applications received **on or after October 1, 2026** (including the remainder of the CY 2028 cycle through March 1, 2027) would have to demonstrate substantial clinical improvement under § 419.66(c)(2)(i). Applications submitted **as of September 30, 2026** for Breakthrough-designated devices could still be approved under the alternative pathway, and existing category codes would keep their 2-to-3-year eligibility. The change would take effect October 1, 2026 if finalized. (Medicare OPPS and ASC Payment Systems Proposed Rule § A)

---

Every device name, applicant, and proposed determination above is drawn directly from the individual application discussions in § IV.A of the rule. Each application discussion includes a CMS overview table (Tables 30–42) and, for additional detail, a link to the applicant's public posting on the CMS MEARIS system.