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Symplicity Spyral™ renal denervation system
New Technology Add-On Payment (NTAP)

Overview

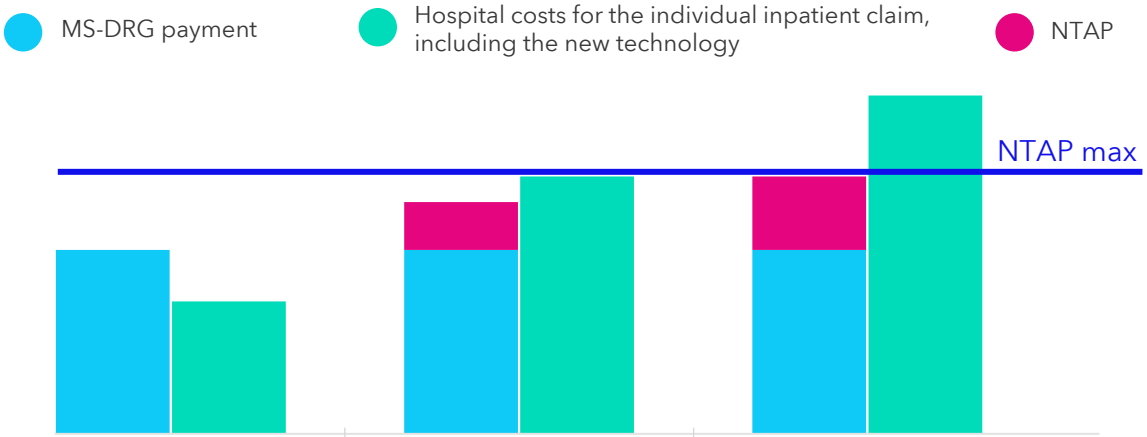
The Symplicity Spyral™ multi-electrode renal denervation (RDN) catheter has been approved by Medicare for NTAP beginning October 1, 2024.[1]

New technology add-on payment (NTAP) is a mechanism to provide hospitals with payment in addition to the MS-DRG payment for select inpatient cases that utilize new technologies specifically approved for this temporary payment program. The NTAP payment amount is calculated as a case-by-case stop-loss: either the lesser of 65% of the difference between the full MS-DRG payment and costs of the case (Case 2 below) or 65% of the estimated cost of the new technology (Case 3 below).[2,3]

Additionally, the following must all be true for a case to be eligible for NTAP:

Patient is a Medicare fee-for-service beneficiary	✓
The procedure using the eligible technology is performed during an inpatient hospitalization	✓
The claim includes the appropriate ICD-10 PCS code: **X05133A**	✓
Costs of the case exceed the standard MS–DRG payment (i.e., cases with operating loss)	✓

NTAP Illustration



Case 1 – No NTAP
Hospital inpatient costs do not exceed MS-DRG payment

Case 2 – Partial NTAP
Hospital inpatient costs exceed MS-DRG payment
NTAP is 65% of difference between costs and payment

Case 3 – Maximum NTAP
Hospital inpatient costs significantly exceed MS-DRG payment
NTAP is capped at 65% of new technology cost

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Frequently Asked Questions

When is the NTAP effective?
Then Symplicity Spyral catheter was approved for NTAP effective October 1, 2024.

Are Medicare Advantage or commercially insured patient claims eligible for NTAP?
No. Medicare Advantage beneficiaries and commercially insured are not eligible for NTAP. Only Medicare fee-for-service beneficiaries are eligible for NTAP.

Are outpatient cases eligible for NTAP?
No. While we expect Symplicity RDN will be performed predominately in the outpatient setting, outpatient procedures are not eligible for NTAP. Medtronic is working toward gaining transitional pass-through payment (TPT), which when effective will apply in the outpatient setting.

Do all inpatient cases using an NTAP eligible technology receive an additional payment?
Not necessarily. Only inpatient Medicare fee-for-service cases where the costs of the case exceed the MS-DRG payment are eligible for NTAP. Additionally, NTAP does not apply to prospective payment system (PPS) exempt hospitals (e.g., certain cancer hospitals and children's hospitals, Maryland hospitals).

How should a Symplicity case be billed in the hospital inpatient setting?
The appropriate ICD-10-PCS code, **X05133A**, should be included on inpatient hospital claims to describe the use of Symplicity for renal denervation. Otherwise, there are no special billing requirements for processing the NTAP payment.

What ICD-10 procedure code should be reported for the NTAP?
CMS established ICD-10 PCS code **X05133A** (Destruction of renal sympathetic nerve(s) using radiofrequency ablation, percutaneous approach, new technology group 10), effective October 1, 2024, to report radiofrequency renal denervation in the inpatient setting. This code should be reported for all inpatient Symplicity RDN cases.

What DRG will Symplicity be assigned to?
Under the Medicare DRG grouper methodology, the Symplicity Spyral RDN procedure will be assigned to DRG 264 Other Circulatory System O.R. Procedures. The national average Medicare payment for DRG 264 is $24,873. Note, the actual DRG assignment for an individual case will vary according to other services included in the claim.

How long does a qualifying technology have NTAP?
NTAP is temporary. The duration is specific to each technology but generally lasts approximately three years.

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How does NTAP impact physician payment?

Physician professional payments are not impacted by NTAP in the inpatient setting.

Is the NTAP amount fixed?

No. The NTAP amount is not a fixed amount - it is calculated as a case-by-case stop loss. The maximum NTAP amount is 65% of the technology cost as determined by CMS.

The payment will also vary based on the final DRG assignment of the case. The maximum NTAP payment for Symplicity Spyral is $10,400.

How are the costs of the case determined if the hospital is only submitting charges?

Medicare calculates the total costs based on the total covered hospital charges for each case and the hospital's inpatient operating cost to charge ratio (CCR) determined from its cost report. Multiplying the hospital charges by the CCR will determine an estimate of the hospital's costs, which is then used to calculate the NTAP, if applicable.

Please visit our Symplicity Reimbursement Homepage for more information.

If you need help understanding NTAP or have other questions, please contact the Medtronic health economics and reimbursement team at:

Phone: 877-347-9662
Email: rs.cardiovascularhealtheconomics@medtronic.com

References

1. IPPS Final Rule Home Page. cms.gov https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipps-final-rule-home-page Updated August 1, 2024. Accessed August 2, 2024
2. New Medical Services and New Technologies. cms.gov, www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/newtech. Accessed 23 Aug. 2023.
3. For current requirements regarding the IPPS NTAP, including the NTAP eligibility criteria, see the statute at sections 1886(d)(5)(K) and (L) of the Social Security Act (the "Act"), the regulations at 42 CFR sections 412.87 and 412.88, and the annual IPPS rulemakings.

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Indications

The Symplicity Spyral™ renal denervation system is indicated to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.

Contraindications

The Symplicity Spyral system is contraindicated in patients with any of the following conditions: • Renal artery diameter < 3mm or > 8mm • Renal artery fibromuscular dysplasia (FMD) • Stented renal artery (<3 months prior to RDN procedure) • Renal artery aneurysm • Renal artery diameter stenosis >50% • Pregnancy • Presence of abnormal kidney (or secreting adrenal) tumor • Iliac/femoral artery stenosis precluding insertion of the catheter.

Warnings and Precautions

A thorough understanding of the technical principles, clinical applications, and risks associated with vascular access techniques and percutaneous transluminal catheterization in renal arteries is necessary before using this device.

The safety and efficacy of the Symplicity Spyral system has not been established in patients with isolated systolic hypertension or in patients with prior renal artery interventions including renal stents, renal angioplasty, or prior renal denervation. The Symplicity Spyral system has not yet been studied in patients who are breastfeeding, under the age of 18, or with secondary hypertension • Avoid treatment with the Symplicity Spyral™ catheter within 5 mm of any diseased area or stent. • Implantable pacemakers (IPGs) and implantable cardioverter defibrillators (ICDs) or other active implants may be adversely affected by RF ablation. Refer to the implantable device's Instructions for Use. • The patient's heart rate may drop during the ablation procedure. • Proper pain medication should be administered at least 10 min before ablating renal nerves.

Potential Adverse Events

Potential adverse events associated with use of the renal denervation device or the interventional procedures include, but are not limited to, the following conditions: • Allergic reaction to contrast • Arterial damage, including injury from energy application, dissection, or perforation, • Arterial spasm, or stenosis • Arterio-enteric fistula • AV fistula • Bleeding • Blood clots or embolism • Bruising • Cardiopulmonary arrest • Complications associated with medications commonly utilized during the procedure, such as narcotics, anxiolytics, or other pain or anti-vasospasm medications • Death • Deep vein thrombosis • Edema Electrolyte imbalance • Heart rhythm disturbances, including bradycardia • Hematoma • Hematoma – retroperitoneal • Hematuria • Hypertension • Hypotension (may cause end organ hypoperfusion) • Infection• Kidney damage including renal failure or perforation • Myocardial infarction • Nausea or vomiting • Pain or discomfort • Peripheral ischemia • Pulmonary embolism • Proteinuria • Pseudoaneurysm • Radiocontrast nephropathy • Renal artery aneurysm •Skin burns from failure of the dispersive electrode pad • Stroke • Other potential adverse events that are unforeseen at this time.

Please reference appropriate product *Instructions for Use* and *User Manual* for more information regarding indications, contraindications, warnings, precautions, and potential adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

For further information, please call and/or consult Medtronic at 800-633-8766 or the Medtronic website at medtronic.com

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