

## Overview

Effective October 1, 2025, the Centers for Medicare and Medicaid Services (CMS) has granted a New Technology Add-on Payment (NTAP) for the Ossera AFX System. The Ossera AFX System (formerly called the restor3d TIDAL™ Fusion Cage System) has been designated by the U.S. Food and Drug Administration (FDA) as a Breakthrough Device with the following indication for use:

**The restor3d TIDAL Fusion Cage System is intended to be used as part of a tibiototalcaneal fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk of limb loss. The restor3d TIDAL Fusion Cage System is intended for use as an accessory to the DynaNail TTC Fusion System. The restor3d TIDAL Fusion Cage System is not intended for standalone use. The restor3d TIDAL Fusion Cage System is intended for use with autograft and/or allogenic bone graft.**

## NTAP Payment Calculation

Hospitals are eligible for an incremental payment of up to \$18,196.75 from Medicare for fee-for-service cases above the standard Medicare Severity Diagnosis-Related Group (MS-DRG) payment amount when the Ossera AFX implant is utilized according to FDA labeling. The NTAP program recognizes new technologies that provide substantial clinical improvement over already available therapies, to support Medicare beneficiaries' timely access to new innovations.

The NTAP eligibility depends on several factors such as hospital-specific MS-DRG payment rate, operating cost-to-charge ratio (CCR), and estimated total cost per case.

Example NTAP Payment Calculations

Example 1: Calculation for an NTAP-**eligible** case

DESCRIPTION		CALCULATION	AMOUNT
Hospital Charges per Case (Entire hospital stay, including device)	A		\$125,000
Hospital-Specific Inpatient CCR (published by Medicare)	B		0.35
Hospital Estimated Cost Per Case	C	A x B	\$43,750
Hospital-Specific MS-DRG Payment	D		\$35,000
Hospital Case Cost Minus Hospital-Specific MS-DRG Reimbursement (Hospital case cost must exceed MS-DRG payment)	E	C - D	\$8,750
65% of Hospital Case Cost Minus Hospital-Specific MS-DRG	F	E x 0.65	\$5,687.50
NTAP Cap (determined by CMS)	G		\$18,196.75
NTAP Payment Amount	H	Lesser of F and G	\$5,687.50
Estimated Total Hospital Reimbursement [NTAP + Hospital-Specific MS-DRG payment]		D + H	\$40,687.50

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## Ossera™ AFX System

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Example 2: Calculation for an NTAP-**ineligible** case

DESCRIPTION		CALCULATION	AMOUNT
Hospital Charges per Case (Entire hospital stay, including device)	A		\$100,000
Hospital-Specific Inpatient CCR (published by Medicare)	B		0.3
Hospital Estimated Cost Per Case	C	A x B	\$30,000
Hospital-Specific MS-DRG Payment	D		\$31,000
Hospital Case Cost Minus Hospital-Specific MS-DRG Reimbursement (Hospital case cost must exceed MS-DRG payment)	E	C - D	(\$1,000)
65% of Hospital Case Cost Minus Hospital-Specific MS-DRG	F	E x 0.65	N/A
NTAP Cap (determined by CMS)	G		\$18,196.75
NTAP Payment Amount	H	Lesser of F and G	\$0
Estimated Total Hospital Reimbursement [NTAP + Hospital-Specific MS-DRG payment]		D + H	\$31,000

## ICD-10-PCS Codes for Ossera AFX

CMS has created the following four ICD-10-PCS New Technology Codes to describe hospital inpatient procedures utilizing an internal fixation device with a gyroid-sheet lattice design. Currently, the Ossera AFX System is the only implant that meets this criterion and is eligible to report this code under the NTAP program.

<b>X</b> New Technology			
<b>R</b> Joints			
<b>G</b> Fusion			
<b>J</b> Ankle Joint, Right	<b>0</b> Open	<b>C</b> Internal Fixation Device, Gyroid-Sheet Lattice Design	<b>A</b> New Technology Group 10
<b>K</b> Ankle Joint, Left	<b>0</b> Open	<b>C</b> Internal Fixation Device, Gyroid-Sheet Lattice Design	<b>A</b> New Technology Group 10
<b>L</b> Tarsal Joint, Right	<b>0</b> Open	<b>C</b> Internal Fixation Device, Gyroid-Sheet Lattice Design	<b>A</b> New Technology Group 10
<b>M</b> Tarsal Joint, Left	<b>0</b> Open	<b>C</b> Internal Fixation Device, Gyroid-Sheet Lattice Design	<b>A</b> New Technology Group 10

## Hospital Inpatient DRG Assignment for Ossera AFX System

Final DRG assignment for cases utilizing the Ossera AFX System will vary based on the ICD-10-PCS and ICD-10-CM code combination reported for the specific patient admission. The following DRGs are representative of commonly assigned DRGs for procedures in which the Ossera AFX System is indicated.

MDC	DRG	DESCRIPTION	2026 MEDICARE NATIONAL AVERAGE PAYMENT
<b>8</b>		<b>Diseases and Disorders of the Musculoskeletal System and Connective Tissue</b>	
	492	Lower extremity and Humerus Procedures, Except Hip, Foot, Femur with MCC	\$26,783
	493	Lower extremity and Humerus Procedures, Except Hip, Foot, Femur with CC	\$18,500
	494	Lower extremity and Humerus Procedures, Except Hip, Foot, Femur without CC/ MCC	\$14,637
<b>10</b>		<b>Endocrine, Nutritional and Metabolic Diseases and Disorders</b>	
	628	Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC	\$27,185
	629	Other Endocrine, Nutritional and Metabolic O.R. Procedures with CC	\$15,894
	630	Other Endocrine, Nutritional and Metabolic O.R. Procedures without CC/ MCC	\$10,646
<b>21</b>		<b>Injuries, Poisonings and Toxic Effects of Drugs</b>	
	907	Other O.R. Procedures for Injuries with MCC	\$28,006
	908	Other O.R. Procedures for Injuries with CC	\$14,554
	909	Other O.R. Procedures for Injuries without CC/ MCC	\$9,576
<b>24</b>		<b>Multiple Significant Trauma</b>	
	957	Other O.R. Procedures for Multiple Significant Trauma with MCC	\$55,584
	958	Other O.R. Procedures for Multiple Significant Trauma with CC	\$30,739
	959	Other O.R. Procedures for Multiple Significant Trauma without CC/ MCC	\$21,476
		<b>DRGs Associated with ALL MDCs</b>	
	981	Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC	\$34,225
	982	Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC	\$17,934
	983	Extensive O.R. Procedures Unrelated to Principal Diagnosis without CC/ MCC	\$12,503

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The following ICD-10-CM diagnosis codes are examples of those that may be reported to support medical necessity for the Ossera AFX System based on the FDA-cleared indication for use. Final coding should be determined by the healthcare provider based on the patient's overall health conditions and medical necessity. This list is not all inclusive and is only representative of those submitted to CMS to support the NTAP application.

A complete list of the ICD-10-CM codes submitted to CMS as part of the restor3d TIDAL Fusion Cage NTAP application can be found on MEARIS™:

<https://mearis.cms.gov/public/publications/ntap/NTP2410022M84U>

ICD-10-CM CODE	TITLE
I96	Gangrene, not elsewhere classified
M00*	Arthritis due to bacteria
M00*	Arthritis due to bacteria
M01*	Direct parasitic infection
M05*	Rheumatoid arthritis with rheumatoid factor
M06*	Other rheumatoid arthritis
M07*	Enteropathic arthropathies
M08*	Juvenile arthritis
M11.879	Other specified crystal arthropathies, unspecified ankle and foot
M12*	Other and unspecified arthropathy
M13*	Other arthritis
M14*	Arthropathies in other diseases classified elsewhere
M19*	Other and unspecified osteoarthritis
M21*	Other acquired deformities of limbs
M24*	Other specific joint derangements
M25*	Other joint disorder, not elsewhere classified
M77*	Other enthesopathies
M80*	Osteoporosis with current pathological fracture
M84*	Disorder of continuity of bone
M86*	Osteomyelitis
M87*	Osteonecrosis
M89*	Other disorders of bone
M90*	Osteopathies in diseases classified elsewhere
Q72*	Reduction defects of lower limb
Q78.0	Other osteochondrodysplasias
S82*	Fracture of lower leg, including ankle
S97*	Crushing injury of ankle and foot

## Frequently Asked Questions

### 1. When does the New Technology Add-On Payment (NTAP) for Ossera AFX start, and how long will it apply?

The NTAP for Ossera AFX took effect on **October 1, 2025**. The add-on payment is eligible for **at least two years** and can extend for up to **three years**.

### 2. What are the hospital billing requirements for the Ossera AFX System in an inpatient setting?

Hospitals are to report the use of the Ossera AFX System (Internal Fixation Device, Gyroid-Sheet Lattice Design) with the appropriate ICD-10-PCS new technology code assigned by CMS to identify the procedure as NTAP eligible for claims processing by Medicare.

### 3. Is the NTAP payment for the Ossera AFX System the same for every inpatient case?

No. Only Medicare fee-for-service procedures are eligible for payment under the NTAP program. The NTAP payment is **not a flat rate** and varies by case. For CY 2026, the **maximum additional amount** a hospital can receive (on top of the full DRG payment) is **\$18,196.75 per discharge**. The actual payment amount varies on several factors including procedure charge, hospital specific CCR, DRG payment, and NTAP cap for the device.

### 4. Is the NTAP payment based on the number of Ossera AFX units used or on a per-discharge basis?

The NTAP is paid **once per discharge**, not per device. However, the **total cost of all Ossera AFX System units used** is included in the overall case charges, which impacts both NTAP eligibility and the calculated amount.

### 5. How is the total reimbursement calculated for an Ossera AFX case that qualifies for NTAP?

If the case qualifies for NTAP, the hospital receives:

- The **full MS-DRG payment**, plus
- **Either 65% of the difference** between the reported discharge cost and the MS-DRG payment, or 65% of the Ossera AFX device ( **\$18,196.75**), **whichever is less**.

The NTAP amount is added to the MS-DRG payment to determine the total payment for the procedure.

### 6. Do commercial payers and Medicare Advantage plans participate in the NTAP payment program similar to fee-for-service Medicare?

No, NTAP payment only applies to cases covered under traditional Medicare (Fee-for-Service Medicare). Commercial payers may have separate pathways for new technology reimbursement (e.g., carve-outs, negotiated rates). Hospitals should verify coverage and payment policies with commercial and Medicare Advantage plans.

### 7. Are the restor3d TIDAL Fusion Cage System and Ossera AFX System the same device?

**Yes.** At the time the NTAP application was submitted, the name of the device was restor3d TIDAL Fusion Cage System. After FDA clearance and upon commercialization, the device name was changed to Ossera AFX System; it is the same device that was approved through the NTAP application process but with a different name.

**CAUTION:** Federal law restricts this device to sale by or on the order of a physician. Prior to use of a restor3d device, please review the package insert, product label, instructions for use and/or surgical technique for a complete listing of indications, contraindications, warnings, precautions, and directions for use.

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#### References:

- CMS 1833-F Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS)
- Medicare Electronic Application Request Information System™ (MEARIS™)
- ICD-10-CM Expert for Hospitals 2026, Optum