Implantable tibial neuromodulation coding and payment guide FAQ

Can you describe the implant procedure for the Medtronic Altaviva™ Neuromodulation system?
The Altaviva™ system procedure involves the open insertion of a subcutaneously implanted device. The Altaviva™ device consists of a single leadless neuromodulation system that contains a pulse generator and an embedded electrode that automatically, and intermittently, stimulates the tibial nerve to treat the symptoms of urgency urinary incontinence (UUI).

Is the Altaviva™ system implant procedure FDA approved?
The Altaviva™ system is an FDA, PMA-approved subcutaneous implantable device indicated for treatment of urgency urinary incontinence (UUI) in patients who failed or could not tolerate more conservative treatments. Medtronic does not promote the off-label use of the implantable Altaviva™ system.

What are the physician RVUs and payment associated with Category III CPT™* codes 0816T and 0818T?
Relative value units (RVUs) are not established for Category III CPT™* codes. In the absence of established RVUs, providing a comparable Category I CPT™* code can assist payers in defining the work and practice expense associated with performing the service or procedure. It is ultimately the physician's responsibility to choose the most appropriate Category I CPT™* crosswalk code that is the best representation of the physician time, work, complexity, and resources required for the Altaviva™ implant procedure. Medicare and commercial payers will determine physician payment for these services on a case-by-case basis following review of documentation, as requested.

How do I identify a comparison CPT™* code representative of the Altaviva™ system implant procedure?
Contact payers for specific instructions. Many payers permit submission of a letter in which you may identify a comparable procedure and determine the similarities in work, time, and expertise, etc. between the Altaviva™ implant procedure and the identified comparable procedure. You may also include any differences between the two (2) procedures including whether the Altaviva™ implant procedure requires more or less work, time, expertise, etc. than the identified comparable procedure (see question below). In addition, it is helpful to provide the RVUs and charges/payments for the identified comparison procedure, and charges for the Altaviva™ system implant procedure. Please refer to the CPT™* Category III Crosswalk Guidance document for full details on physician reporting and potential crosswalk comparators.

What steps are necessary when billing a Category III CPT™* code?
Contact payers for payer-specific billing instructions. When reporting a service using a Category III CPT™* code, it is a best practice to use the freeform field of the claim form (box 19) to list the identified comparison CPT™* code, including its 2025, geographically adjusted Medicare allowed amount. This may help the payer understand how you came up with your charge. For example, "*0816T (Altaviva™ implant Category III CPT™* code) comparable to XXXXX (identified comparator CPT™* code), expected payment amount $XXX. XX.*" It is important to remember payers will make their own payment determination for Category III CPT™* codes. Payers may request supporting documentation, which could include a cover letter, an operative report, and medical records. Please refer to the CPT™* Category III Crosswalk Guidance document for full details on physician reporting, potential crosswalk comparators, and recommended supporting documentation for claim submission.

Does Medicare require the submission of medical necessity documentation when submitting a claim for the Altaviva™ system implant?
Providers should always document medical necessity of the Altaviva™ system implant for their patients. Medicare provides coverage for "medically reasonable and necessary" services; reasonable and necessary guidelines are accessible by going to the Novitas (a Medicare Administrative Contractor, commonly referred to as a MAC) website.

Because the Altaviva™ system implant procedure is reported under Category III CPT™* code 0816T, it is required for Novitas, and strongly recommended for all other MACs, that the following documentation be submitted with the initial claim submission: 1) History and physical notes; 2) lab/diagnostic test results, if applicable; 3) progress/office notes specific to the patient's condition; 4) operative/procedure report for the Altaviva™ implant procedure; 5) relevant peer

reviewed articles; 6) society guidelines, if available; and 7) any additional documentation that supports the need for the Altaviva™ system implant procedure.

When required by the MAC, if documentation is not submitted to support the Category III CPT™* code billed, the service will be rejected, and the claim must then be resubmitted with the required information.

Can I use CPT™* code 64590 to report the Altaviva™ system implant procedure in 2025?
As a result of coding changes in 2024, CPT™* code 64590 no longer appropriately describes the Altaviva™ implant procedure. AMA CPT™* requires providers to code to the highest level of specificity to report a patient's condition and services rendered. Effective January 1, 2024, Category III CPT™* code 0816T most accurately describes the implantable Altaviva™ implant procedure.

Are there supporting materials, including example letters, for use in prior authorization requests or appeals?
Providers are solely responsible for preparing and submitting prior authorization requests and/or appeal documentation, which includes ensuring the information included accurately reflects the patient's condition. Our Implantable Tibial Neuromodulation (ITNM) Patient Access Resource, however, may be helpful when creating patient-specific prior authorization requests to submit to payers. HCPs may also utilize Medtronic's Patient Access Support (PAS) which provides support with the prior authorization process, and if necessary, appeals. Despite most payers requiring prior authorization or predetermination, it is not a guarantee of payment.

Is the Altaviva™ system implant procedure covered by insurance?
Medical policies, coverage determination guidelines, and utilization review guidelines are developed by payers, as needed, for services and procedures and are subject to change without notice. Policies and guidelines may be available on payer websites, so Medtronic recommends that providers check to determine what criteria must be met for the procedure to be considered medically necessary. In the absence of written policy, medical necessity determinations are made on a case-by-case basis. To improve the likelihood of payment, Medtronic does not recommend proceeding with commercial or Medicare Advantage cases unless prior authorization or predetermination has been obtained.

What Medicare coverage guidance is available for the Altaviva™ system implant procedure?
There are currently no national coverage determinations (NCDs) or local coverage determinations (LCDs) applicable to the Altaviva™ system implant procedure. In the absence of an NCD or LCD, individual Medicare Administrative Contractors (MACs) will review claims on a case-by-case basis pursuant to Section 1862(a)(1)(A) of the Social Security Act.[6]

Is there a staged test or trial required prior to implanting the Altaviva™ system?
There are currently no Medicare NCDs or LCDs for the Altaviva™ system implant procedure, therefore, there are no requirements for staged tests or trials prior to the Altaviva™ implant for Medicare FFS beneficiaries. Commercial payers and Medicare Advantage plans may, however, have their own medical necessity requirements.

Do payers require prior authorization for the Altaviva™ system implant procedure?

- Traditional Medicare Fee-For-Service: may cover the Altaviva™ system implant procedure. Medicare does not require prior authorizations for services that are considered benefits under Medicare. In the absence of an LCD, however, it may be beneficial to contact the local Medicare Administrative Carrier (MAC) for possible medical necessity guidelines or instructions.
- Medicare Advantage Plans: typically follow Medicare guidelines, but in the absence of an LCD, they may have additional coverage criteria. Contact the payer to verify medical necessity and prior authorization requirements.
- Commercial Payers: may require prior authorization. Contact the payer to determine eligibility and determine if prior authorization is required. The sample letter of medical necessity in our ITNM Patient Access Resource can be used as a template if prior authorization is required.

For additional information regarding the prior authorization process, please refer to our ITNM Patient Access Resource. For assistance with prior authorization, please contact our Patient Access Support Call Center by email at RS.PriorAuthorizationInquiry@medtronic.com or register directly through our HCP portal at paportal.medtronic.com.