

November 4, 2014

DISTAR LLC
7208 JEFFERSON ST NE SUITE B
ALBUQUERQUE NM 87109

Re: Assigned HCPCS Codes for DME Billing

Xref: 35112466

ADJUSTABLE THERASNORE (SMALL ARCH)	DISTAR LLC	13110S	E0485
ADJUSTABLE THERASNORE (STANDARD ARCH)	DISTAR LLC	13110	E0485
ADJUSTABLE THERASNORE (LARGE ARCH)	DISTAR LLC	13110L	E0485

Dear Rick Mondick:

The Pricing, Data Analysis, and Coding (PDAC) Contractor has reviewed the product(s) listed above and has approved the listed Healthcare Common Procedure Coding System (HCPCS) code(s) for billing the four Durable Medical Equipment Medicare Administrative Contractors (DME MACs).

The PDAC Contractor provides coding assistance to manufacturers to ensure proper coding of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). The PDAC publishes coding decisions based on the coding guidelines established by the Local Coverage Determinations (LCDs) and associated Policy Articles and any related Advisory Articles established by the DME MACs. All products submitted to the PDAC for a coding verification review are examined by coders and professionals following a formal, standardized process.

The PDAC has reviewed the above listed product(s). The above listed product(s) has been reviewed. Based on this review and application of DME MAC policy, the HCPCS code(s) listed below should be used when billing the DME MACs:

E0485 - Oral Device/Appliance Used To Reduce Upper Airway Collapsibility, Adjustable Or Non-Adjustable, Prefabricated, Includes Fitting And Adjustment

The Local Coverage Article for Oral Appliances for Obstructive Sleep Apnea-Policy Article-Effective November 2013 states:

A custom fabricated oral appliance (E0486) is one which is individually and uniquely made for an individual beneficiary. It involves taking an impression of the beneficiary's teeth and making a positive model of plaster or equivalent material. Basic materials are cut, bent, and molded using the positive model. It requires more than trimming, bending,

or making other modifications to a substantially prefabricated item. A custom fabricated oral appliance may include a prefabricated component (e.g., the joint mechanism).

Code E0486 may only be used for custom fabricated mandibular advancement devices. To be coded as E0486, custom fabricated mandibular advancement devices must:

1. Have a fixed mechanical hinge (see below) at the sides, front or palate, and,
2. Have a mechanism that allows the mandible to be advanced in increments of one millimeter or less, and,
3. Be able to protrude the mandible beyond the front teeth at maximum protrusion, and,
4. Be adjustable by the beneficiary in increments of one millimeter or less, and,
5. Retain their adjustment setting when removed, and,
6. Maintain mouth position during sleep so as to prevent dislodging the device.

A fixed hinge is defined as a mechanical joint, containing an inseparable pivot point. Interlocking flanges, tongue and groove mechanisms, hook and loop or hook and eye clasps, elastic straps or bands, etc. (not all-inclusive) do not meet this requirement.

Items that require repeated adjustments and modification beyond the initial 90-day fitting and adjustment period in order to maintain fit and/or effectiveness are not eligible for classification as DME. These items are considered as dental therapies, which are not eligible for reimbursement, by Medicare under the DME benefit. They must not be coded using E0486.

Custom fabricated mandibular advancement devices that do not incorporate all of the criteria (1-6) above must be coded as A9720. Do not use HCPCS code E0486.

A prefabricated oral appliance (E0485) is one, which is manufactured in quantity without a specific beneficiary in mind. A prefabricated oral appliance may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific beneficiary (i.e., custom fitted). Any appliance that does not meet the definition of a custom fabricated oral appliance is considered prefabricated. E0485 is used for all prefabricated oral appliances used for the treatment of OSA including, but not limited to, mandibular advancement devices, tongue positioning appliances, etc.

The product provided for coding is a prefabricated oral appliance that does not have a fixed hinge and does not meet coding requirements for code E0486; therefore code E0485 is assigned.

This decision applies to the application we received on August 19, 2014. If information submitted in that application has changed or were to change, it could impact our decision. Therefore, a new application would need to be submitted for HCPCS coding verification review. The coding assigned in this decision letter will be available on the Product Classification List (PCL) on the Durable Medical Equipment Coding System (DMECS) within ten (10) working days from the letter's date. The DMECS can be accessed on the PDAC website,

www.dmepdac.com. Please take the time to verify that this coding decision is correctly reflected in DMECS.

If you disagree with this decision, you may request a reconsideration within 45 days of the letter's date and provide evidence to substantiate a reconsideration of PDAC's original coding determination. To request a reconsideration, complete the Reconsideration Request form located on the PDAC website at <https://www.dmepdac.com/review/requesting.html>. If your request for a reconsideration is made after the 45-day time frame, it will require a new application and documentation to support the request.

It is the responsibility of manufacturers and distributors to notify the PDAC immediately of any changes involving their products, as listed on the PCL on DMECS. Further information for requesting updates to the PCL can be found on the PDAC website at <https://www.dmepdac.com/review/notifying.html>. It is also the responsibility of manufacturers and distributors to assure their websites and product marketing materials accurately reflect the product reviewed by the PDAC and the coding decision assigned.

An assignment of the HCPCS code(s) to product(s) is not an approval or endorsement of the product(s) by Medicare or Noridian Healthcare Solutions; nor does it imply or guarantee claim reimbursement or coverage.

If you have questions about policy, claim coverage or reimbursement, please contact the DME MAC for your jurisdiction. For other questions, contact the PDAC Contact Center at the address listed above or by telephone at (877) 735-1326. The Contact Center is open Monday through Friday from 8:30 a.m. to 4 p.m. CT.

Sincerely,

PDAC
Noridian Healthcare Solutions, LLC
www.dmepdac.com