



## mRNA and mmRNA APPLIANCE

### Medical and Dental Coding and Billing

#### Vivos Therapeutics, Inc.

#### **Purpose**

Vivos Therapeutics, Inc. (“Vivos”) recognizes the need to have a clear, written direction for procedure coding and billing for its mandibular advancement devices. The mmRNA (modified mandibular Repositioning Nighttime Appliance) medical device has 510(k) clearance from the FDA as a Class II medical device for jaw repositioning and the treatment of mild-to-moderate sleep apnea and snoring in adults. The mRNA has mandibular advancement capability but does not have the same FDA clearance as the mmRNA.

#### **Clinical application**

Sleep apnea is a medical condition diagnosed by a physician. A range of therapies is available to treat this condition including oral appliance therapy for some patients. Oral appliances used to treat sleep apnea utilize mandibular advancement to increase airway volume at night during sleep. The mRNA and mmRNA devices are custom fabricated mandibular advancement oral appliances.

#### **Procedure Codes: HCPCS and CDT**

##### *Medical (HCPCS)*

Level II of the HCPCS is used primarily to identify products, supplies, and services not included in the CPT including codes for DME (Durable Medical Equipment). Mandibular advancement oral appliances ordered by a physician to treat OSA are considered to be DME. HCPCS code E0486 is used for billing of such appliances to medical insurance: ORAL DEVICE/APPLIANCE USED TO REDUCE UPPER AIRWAY COLLAPSIBILITY, ADJUSTABLE OR NON-ADJUSTABLE, CUSTOM FABRICATED, INCLUDES FITTING AND ADJUSTMENT. Both the mRNA and mmRNA satisfy this definition.

##### *Dental (CDT)*

Effective 1/1/2022 the CDT contains dental procedure codes related to sleep apnea appliance therapy:

- D9947- Custom sleep apnea appliance fabrication and placement
- D9948- Adjustment of custom sleep apnea appliance
- D9949- Repair of custom sleep apnea appliance

Both the mRNA and mmRNA satisfy the description of CDT D9947 for dental billing purposes.

## **Guidelines for billing of the mRNA and mmRNA**

Treatment of OSA is a medical service covered by medical insurance. **Reimbursement is first obtained from medical payers** and secondarily from supplemental insurance such as dental coverage.

### *Commercial medical and dental insurance*

**E0486** Preauthorization for mandibular advancement OA must meet the clinical guidelines of the particular payer (i.e. documentation of the diagnosis of OSA by a sleep physician, prescription for the OA by the treating MD, etc.) A medical claim is then submitted first to the medical carrier for benefits payable for the custom appliance (mRNA or mmRNA) coded as E0486. Adjustment of the appliance is included in the code E0486 for a 90-day post delivery period and adjustments during that global period are not billable to medical insurance.

**D9947** After the medical claim is adjudicated and paid, a dental claim for benefits is submitted using CDT code D9947. Preauthorization requirements of dental payers for this code are unknown at this time. Should the aggregate payment of both medical and dental claims exceed the dentist's full fee, a refund of the overpayment is appropriate. The dental code D9947 does not contain a global period. The post delivery adjustments are billable to dental plans with the code D9948.

### *Medicare*

**E0486** is billable to Medicare by VIPs enrolled as DME suppliers only. Medicare does not require preauthorization of code E0486; however, Medicare has additional criteria for payment of code E0486 requiring certain physical features and characteristics of the appliance to qualify for benefits. According to CMS, to be coded as E0486, custom fabricated mandibular advancement devices must meet all of the criteria below:

- Have a fixed mechanical hinge at the sides, front or palate; and,
- Be able to protrude the individual beneficiary's mandible beyond the front teeth when adjusted to maximum protrusion; and,
- Incorporate a mechanism that allows the mandible to be easily advanced by the beneficiary in increments of one millimeter or less; and,
- Retain the adjustment setting when removed from the mouth; and,
- Maintain the adjusted mouth position during sleep; and,
- Remain fixed in place during sleep so as to prevent dislodging the device; and,
- Require no return dental visits beyond the initial 90-day fitting and adjustment period to perform ongoing modification and adjustments in order to maintain effectiveness (see below)

The mmRNA appliance meets the description and requirements for this code. The mmRNA is included in Medicare's PDAC list of approved oral appliances and is therefore billed to Medicare with code E0486. The

mRNA is not included in PDAC and is not billable to Medicare or to any commercial insurance using Medicare guidelines. Following adjudication of a claim for E0486, Medicare automatically forwards a claim for additional benefits to any Medicare supplement the patient may have. Benefits for claims made by non-participating DME suppliers (without assignment of benefits) are paid directly to the patient.

**D9947** After the Medicare claim is adjudicated and paid, a dental claim for benefits is submitted to any additional, separate dental coverage the patient may have with CDT code D9947. Preauthorization requirements of dental payers for this code are unknown at this time. The dental code D9947 does not contain a global period. Post delivery adjustments are billable to dental plans with the code D9948. Should the aggregate payment of both medical and dental claims exceed the dentist's full fee, a refund of the overpayment is appropriate.

Vivos Therapeutics recommends VIP practices utilize the same specific protocol described herein for patients treated with the mRNA and mmRNA.