	Statement for Insuran	ce Reimbursement (Super-Bill)
	Full Name:	
ler	Business Name:	
Provider	NPI Number:	
Pro	License Number:	
	Business Adress:	
	Full Name:	
	DOB:	
ent	Address:	
Patient		
<b>L</b>	Insurance Company:	Group Number:
	ID Number:	

# **DX:** Diagnosis codes

M26.603 - Bilateral Temporomandibular joint disorder unspecified

□ M62.83/M62.828 - Muscle Spasm □ M26.51- Abnormal closure of mandible **M26.601**- Right Temporomandibular

□ M26.602- Left Temporomandibular joint

- □ M26.4 Malocclusion
- G47.63- Bruxism/Clenching
- G43.909 Migraine
- G44.2 Tension Type Headache

# **TX: Treatment codes**

Date	Service Code	Description	Unit(s)	Fee
	99203	Office or other outpatients visit for the evaluation		
	70486	Computer tomography, Maxillofacial area		
	E0730/E0720	ULF TENS (Transcutaneous electrical nerve stimulation)		
	95868	Electromyography procedures/EMG		
	21299	Myoaligner Device (FDA Cleared)		
		Total Charges:		

Note:

Signature:

## Indications for Use

510(k) Number (*if known*) K230548

Device Name Myoaligner Appliance

#### Indications for Use (Describe)

For protection against teeth grinding, bruxism, and jaw clenching; protection of restorations from injury due to bruxism or clenching; relief of bruxism related headaches, migraines and pain; short-term relief from muscle spasm due to occlusal interference; prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscles; and temporary treatment of temporal mandibular disorder (TMD) along with the relief of associated headaches and pains in adults 18 years of age or older.

Type of Use (Select one or both, as applicable)						
Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Counter Use (21 CFR 801 Subpart C)					

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov* 

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