ORAL APPLIANCES AND ORAL SURGICAL SPLINTS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Oral Appliances:
Oral appliances are removable acrylic appliances worn over the teeth which are used for minimizing the effects of occlusal factors, treating temporomandibular joint (TMJ) diseases non-surgically and treating TMJ-related disorders such as capsulitis, myalgia, bruxism, oral dyskinesia, headache and oral dystonia. They may be custom-made or not custom-made and purchased over-the-counter.

Oral appliances include, but are not limited to:

- Anterior bite stops
- Joint Motion Rehabilitation Devices
- Night guards
- Nociceptive Trigeminal Inhibitors
- Nociceptive Trigeminal Inhibition Tension Suppression Systems (NTI-tss devices)
- Occlusal guards/splints
- Occlusal orthotic devices

Oral Surgical Splints:
Oral surgical splints are used in association with oral surgical procedures. They are also used to treat TMJ diseases non-surgically and for treating TMJ-related disorders such as locked jaw, capsulitis, myalgia, oral dyskinesia and oral dystonia. To make or fabricate an oral surgical splint, an impression is made of the area and the physician customizes the splint from the cast model of the impression.

One oral surgical splint is described as either a mandibular (lower) splint or a maxillary (upper) splint. One or both may be used in the non-surgical treatment of TMJ diseases or the TMJ-related disorders listed above (i.e., locked jaw, etc.).

An oral surgical splint may also be known as:

- Flat lower splint
- Maxillary anterior repositioning splint
- Maxillary stabilization appliance
- Stabilization appliance
ORAL APPLIANCES AND ORAL SURGICAL SPLINTS (cont.)

Criteria:

Oral Appliances:

For oral appliances for the treatment of obstructive sleep apnea syndrome or snoring, see BCBSAZ Medical Coverage Guideline #O782, “Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome”.

- Custom made oral appliances for the non-surgical treatment of TMJ diseases and TMJ-related disorders are considered medically necessary.

  TMJ-related disorders include, but are not limited to:
  - Bruxism
  - Capsulitis
  - Myalgia
  - Oral dyskinesia
  - Oral dystonia

- Custom made oral appliances for the treatment of headaches, including migraine headaches, are considered experimental or investigational based upon:
  1. Insufficient evidence to support improvement of the net health outcome, and
  2. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

- Non-custom made oral appliances obtained over-the-counter are a benefit plan exclusion and not eligible for coverage.

- Jaw motion rehabilitation devices for the treatment of trismus, dysfunction, and hypomobility to maintain joint range of motion, stretching, and muscle strengthening is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.
ORAL APPLIANCES AND ORAL SURGICAL SPLINTS (cont.)

Criteria: (cont.)

Oral Surgical Splints:

Surgical Use:

For oral surgical splints used in association with orthognathic surgery, refer to BCBSAZ Medical Coverage Guideline #O298, “Orthognathic Surgery”.

- An oral surgical splint is considered **medically necessary** with documentation that the splint is fabricated by the surgeon and used in association with an oral surgical procedure.

Non-Surgical Use:

- One oral surgical splint prescribed by a dental provider is considered **medically necessary** for the non-surgical treatment of TMJ disease or TMJ-related disorders:

  TMJ-related disorders include, but are not limited to:

  - Bruxism
  - Capsulitis
  - Locked jaw
  - Myalgia
  - Oral dyskinesia
  - Oral dystonia

- A second oral surgical splint within a six month period is considered **medically necessary** when a separate mandibular splint for daytime use is needed due to an individual’s inability to wear a maxillary splint while speaking.

- Requests for more than one oral surgical splint within a six month period will be reviewed by the medical director(s) and/or clinical advisor(s).

- The following treatments for TMJ disease or TMJ-related disorders are considered **not medically necessary** based upon the procedure being inconsistent with the diagnosis submitted:

  1. More than one oral surgical splint within a six month period for the non-surgical treatment of TMJ disease or TMJ-related disorders that do not meet above criteria
  2. Oral surgical splint for all other indications not previously listed
ORAL APPLIANCES AND ORAL SURGICAL SPLINTS (cont.)

Resources:

Literature reviewed 07/18/17. We do not include marketing materials, poster boards and non-published literature in our review.

ORAL APPLIANCES AND ORAL SURGICAL SPLINTS (cont.)

**Resources:** (cont.)

FDA 510K Summary for NTI Tension Suppression System:

- FDA-approved indication: To be used in the prophylactic treatment of medically diagnosed migraine pain as well as migraine associated tension-type headaches, by reducing their signs and symptoms through reduction of trigeminally innervated muscular activity, and; for the prevention of bruxism and TMJ syndrome through reduction of trigeminally innervated muscular activity.
ORAL APPLIANCES AND ORAL SURGICAL SPLINTS (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ’s Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe’é atah níliníí Blue Cross Blue Shield of Arizona haadá yít’éego bina’idílkidgo éi doodago Hááda bíjá aniyeedííí t’áadoo le’é yina’idílkidgo beehaz’ámii hóló díí t’áá hazaad’μíí háká a’dwoolgo bee haz’a doo bąq háh ilínígóó. Aña halne’ííí kojí bich’íí hodíílníí 877-475-4799.

Chinese: 如果您，或是您正在协助的对象，有关于插入项目名称 Blue Cross Blue Shield of Arizona 方面的问题，您有权免费以您的母语得到帮助和讯息。洽询一位翻译员，可拨打电话 在此插入数字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thể thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thợ dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعده أسئلة بخصوص الخدمة موصولة الضرورية ببلاغ من دون أي تكلفة. للتحدث مع مترجم الصلح ب 877-475-4799.
ORAL APPLIANCES AND ORAL SURGICAL SPLINTS (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay mga katauhan tungkol sa Blue Cross Blue Shield of Arizona, may karanasan ka na makakaya ng tulong at impormasyon sa iyong wiqa ng walang gastos. Upang makaasap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 정가 또는 정가가 되는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 정가는 그러한 도움과 정보를 정가의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay mga katauhan tungkol sa Blue Cross Blue Shield of Arizona, may karanasan ka na makakaya ng tulong at impormasyon sa iyong wiqa ng walang gastos. Upang makaasap ang isang tagasalin, tumawag sa 877-475-4799.

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