BSC2.01	Cleft Palate - Dental Related Services		
Original Policy Date:	April 2, 2010	**Effective Date:**	April 1, 2024
Section:	2.0 Medicine	**Page:**	Page 1 of 7

Policy Statement

I. In interpreting whether a proposed procedure meets the definition of reconstructive surgery, as defined by law, the procedure may be denied as **not medically necessary** under **any** of the following conditions:
   A. The procedure is likely to result in only minimal improvement in appearance, in accordance with the standard of care as practiced by providers specializing in reconstructive surgery
   B. The treating surgeon cannot or will not provide sufficient documentation, including (when appropriate) medical quality color photographs, appropriate radiographs, and documentation of medical necessity (in medical records or a separate letter) which accurately depicts the extent of the clinical problem (see Policy Guidelines and Documentation for Clinical Review sections)
   C. There is alternative approved medical or surgical intervention with equal or superior clinical outcomes
   D. The procedure is for cosmetic purposes only

II. Dental or orthodontic services that are an integral part of reconstructive surgery for cleft palate procedures, as defined by Senate Bill 630 (an amendment to the Reconstructive Surgery Act [AB 1621]), may be considered **medically necessary**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Children born with cleft lip/palate have multiple and complex problems, including dentofacial and orthodontic abnormalities. Medical management of these children may involve dental care. According to Senate Bill 630, an amendment to the Reconstructive Surgery Act (AB 1621) "reconstructive surgery shall include medically necessary dental or orthodontic services that are an integral part of reconstructive surgery…for **cleft palate procedures**." The amendment to the Reconstructive Surgery Act defines cleft palate as "a condition that may include cleft palate, cleft lip, or other craniofacial anomalies associated with cleft palate."[1]

For the purposes of this policy, "integral" is defined as the dental or orthodontic services that are related to, and medically necessary, to provide or complete reconstructive surgery for cleft palate. Typically, these services are performed on children up to and through 10 years of age; however, Blue Shield of California recognizes there may be exceptions and those will be considered on a case-by-case by a Medical Director.

For the purpose of this policy, the qualified reviewer will differentiate a normal structure from an abnormal one based on **any** of the following elements:

- The availability of published normative data for specific anatomic measurements (e.g., cephalometric data for orthognathic surgery)
- The normal structures wide range of accepted variations in diverse populations (e.g., nasal size and shape)
- The presence of a cosmetic implant, in the absence of adjacent native tissue structural pathology, does not constitute an abnormal structure (e.g., cosmetic unilateral, bilateral or asymmetrical saline breast implants)

In determining whether or not a procedure is likely to result in more than minimal improvement in appearance, the qualified reviewer will consider both the size and location of the structural abnormality.

Dental and orthodontic services are generally excluded from coverage under the member's medical benefit. As an exception, dental and orthodontic claims related to reconstructive surgery for cleft palate are a medical benefit. These medically designated services are available to the member whether or not there is an orthodontic benefit included in the member's dental plan.

Documentation must include radiographs and photographs of the jaws, teeth, lateral skull, full face, intraoral radiographs, cephalometric analysis and the completion of the DC016 (Handicapping Labio-Lingual Deviation (HLD) Index California Modification Score Sheet) if orthodontic treatment is contemplated or requested.

Cosmetic services are defined as procedures involving or relating to treatment intended to restore or improve a person's appearance. Documentation must include the rationale of medical necessity stating why the requested procedure will better restore the FUNCTION of the structure and what alternatives (if any) have been attempted

Description

Cleft lip and cleft palate occur when the tissue of a baby's lip or mouth do not join completely or properly during the first trimester of pregnancy. Children with this type of birth defect often experience difficulty with feeding, speech, and hearing as well as having dentofacial and orthodontic abnormalities.

Related Policies

- Orthognathic Surgery
- Reconstructive Services

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

State:
The California Reconstructive Surgery Act (Health & Safety Code Section 1367.63 and the Insurance Code Section 10123.88) defines "reconstructive surgery" as surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do **either** of the following (see also Blue Shield of California Medical Policy: Reconstructive Services):

1) Create a normal appearance to the extent possible

2) Improve function

Rationale

Background

According to the Centers for Disease Control and Prevention (CDC), it is estimated that each year in the United States:

- About 1 in every 1,600 babies is born with cleft lip with cleft palate.
- About 1 in every 2,800 babies is born with cleft lip without cleft palate.
- About 1 in every 1,700 babies is born with cleft palate.[2]

Children born with a cleft palate frequently require "several different types of services, such as surgery, dental and orthodontic care, and speech therapy, all of which need to be provided in a coordinated manner over a period of years. This coordinated care is provided by interdisciplinary cleft palate and/or craniofacial teams comprised of professionals from a variety of health care disciplines."[3]

Literature Review

The California Reconstructive Surgery Act (Health & Safety Code Section 1367.63 and the Insurance Code Section 10123.88) defines "reconstructive surgery" as surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do **either** of the following:

- Create a normal appearance to the extent possible
- Improve function

Senate Bill 630 was proposed as an amendment to the Reconstructive Surgery Act. The bill specifically states:

> "As of July 1, 2010, "reconstructive surgery" shall include medically necessary dental or orthodontic services that are an integral part of reconstructive surgery…for cleft palate procedures. For the purposes of this section "cleft palate" means a condition that may include cleft palate, cleft lip, or other craniofacial anomalies associated with cleft palate."[1]

Senate Bill (SB) 630 mandates that reconstructive surgery for cleft palate shall include medically necessary dental or orthodontic services for cleft palate.

From a clinical perspective, a sequential approach is required to manage and treat cleft lip and/or cleft plate with integration of dental, orthodontic, and surgical procedures. Treatment may vary depending on the extent of repair required and the specific goals to be accomplished. "In addition to primary surgical closure of the cleft lip and cleft palate, many patients will require secondary surgical procedures involving the lip, nose, palate, and jaws. These procedures usually are staged from infancy through adulthood. In all cases, surgical techniques should be individualized according to the needs and condition of the patient."[4]

Summary of Evidence

It is the intent of Blue Shield of California, to apply definitions and make medical necessity determinations consistent with Senate Bill 630, the amendment to the Reconstructive Surgery Act. For the purposes of this policy, "integral" is defined as the dental or orthodontic services that are related to, and medically necessary, to provide or complete reconstructive surgery for cleft palate.

References

1. Steinberg B and Alquist E. Senate Bill SB 630. Accessed March 11, 2024 from http://www.leginfo.ca.gov/pub/09-10/bill/sen/sb_0601-0650/sb_630_bill_20091011_chaptered.html
2. Centers for Disease Control and Prevention (CDC). Facts about Cleft Lip and Cleft Palate. 2023. Accessed March 11, 2024 from http://www.cdc.gov/ncbddd/birthdefects/cleftlip.html
3. Steinberg. Staff Analysis of Senate Bill SB 630. 2009. Accessed March 11, 2024 from http://www.leginfo.ca.gov/pub/09-10/bill/sen/sb_0601-0650/sb_630_cfa_20090413_154014_sen_comm.html
4. American Cleft Palate-Craniofacial Association. Parameters for Evaluation and Treatment of Patients with Cleft Lip/Palate or Other Craniofacial Anomalies. 2024. Accessed March 11, 2024 from http://acpa-cpf.org/team-care/standardscat/parameters-of-care/

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Treatment plan
- Quality diagnostic imaging reflecting the deformity (e.g., intraoral, jaw and teeth)
- Quality medical photographs of the deformity

Post Service (in addition to the above, please include the following):

- Operative report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	21076	Impression and custom preparation; surgical obturator prosthesis
	21079	Impression and custom preparation; interim obturator prosthesis
	21080	Impression and custom preparation; definitive obturator prosthesis
HCPCS	D5922	nasal septal prosthesis
	D5931	obturator prosthesis, surgical
	D5932	obturator prosthesis, definitive
	D5933	obturator prosthesis, modification
	D5936	obturator prosthesis, interim
	D5951	feeding aid
	D5955	palatal lift prosthesis, definitive
	D5958	palatal lift prosthesis, interim
	D8010	limited orthodontic treatment of the primary dentition
	D8020	limited orthodontic treatment of the transitional dentition

Type	Code	Description
	D8030	limited orthodontic treatment of the adolescent dentition
	D8040	limited orthodontic treatment of the adult dentition
	D8070	comprehensive orthodontic treatment of the transitional dentition
	D8080	comprehensive orthodontic treatment of the adolescent dentition

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
04/02/2010	New Policy
07/31/2015	Coding update
04/01/2016	Policy revision without position change
04/01/2017	Policy revision without position change
04/01/2018	Policy revision without position change
07/01/2018	Policy statement clarification
03/01/2019	Policy revision without position change
05/01/2020	Annual review. No change to policy statement.
05/01/2021	Annual review. No change to policy statement. Literature review updated.
02/01/2022	Coding update.
06/01/2022	Annual review. Policy statement and guidelines updated.
04/01/2023	Annual review. Policy statement and guidelines updated.
04/01/2024	Annual review. Policy statement updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	**AFTER** Blue font: Verbiage Changes/Additions
Cleft Palate - Dental Related Services BSC2.01 **Policy Statement:** The California Reconstructive Surgery Act (Health & Safety Code Section 1367.63 and the Insurance Code Section 10123.88) defines "reconstructive surgery" as surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do **either** of the following (see also Blue Shield of California Medical Policy: Reconstructive Services): 1) Create a normal appearance to the extent possible 2) Improve function I. In interpreting whether a proposed procedure meets the definition of reconstructive surgery, as defined by law, the procedure may be denied as **not medically necessary** under **any** of the following conditions: A. The procedure is likely to result in only minimal improvement in appearance, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery B. The treating surgeon cannot or will not provide sufficient documentation, including (when appropriate) medical quality color photographs, appropriate radiographs, and documentation of medical necessity (in medical records or a separate letter) which accurately depicts the extent of the clinical problem (see Policy Guidelines and Documentation for Clinical Review sections) C. There is alternative approved medical or surgical intervention with equal or superior clinical outcomes D. The procedure is for cosmetic purposes only II. Dental or orthodontic services that are an integral part of reconstructive surgery for cleft palate procedures, as defined by Senate Bill 630 (an amendment to the Reconstructive Surgery Act [AB 1621]), may be considered **medically necessary**.	**Cleft Palate - Dental Related Services BSC2.01** **Policy Statement:** I. In interpreting whether a proposed procedure meets the definition of reconstructive surgery, as defined by law, the procedure may be denied as **not medically necessary** under **any** of the following conditions: A. The procedure is likely to result in only minimal improvement in appearance, in accordance with the standard of care as practiced by providers specializing in reconstructive surgery B. The treating surgeon cannot or will not provide sufficient documentation, including (when appropriate) medical quality color photographs, appropriate radiographs, and documentation of medical necessity (in medical records or a separate letter) which accurately depicts the extent of the clinical problem (see Policy Guidelines and Documentation for Clinical Review sections) C. There is alternative approved medical or surgical intervention with equal or superior clinical outcomes D. The procedure is for cosmetic purposes only II. Dental or orthodontic services that are an integral part of reconstructive surgery for cleft palate procedures, as defined by Senate Bill 630 (an amendment to the Reconstructive Surgery Act [AB 1621]), may be considered **medically necessary**.