



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA  
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 04/05/24  
LAST REVIEW DATE: 04/05/24  
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NEXT ANNUAL REVIEW DATE: 2ND QTR 2025

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## LEFORT I OSTEOTOMY

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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 Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria 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.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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## **LEFORT I OSTEOTOMY**

### **Description:**

Orthognathic surgery is performed to correct mandible and/or maxilla abnormalities that may be:

- Present at birth (congenital)
- A skeletal anomaly that may become evident as the individual grows and develops
- The result of traumatic injuries
- The result of an illness or disease process
- The result of surgery or therapeutic intervention

These abnormalities may be present at birth or may develop during growth and development, causing functional, progressive deterioration, cosmetic, and/or psychosocial issues.

The LeFort I osteotomy is a maxillary osteotomy done horizontally to correct midface deformities allowing movement anteriorly/posteriorly, vertically, rotationally, and with segmentation expansion. It is a common surgical procedure done to realign the upper jaw and teeth to correct functional issues and improve appearance. The Lefort I osteotomy can also be used to enable access for the surgical removal of tumors or the reduction of midfacial fractures that are complicated.

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### **Criteria:**

#### **Facial Skeletal Discrepancy:**

- Radiological documentation of **ONE** of the following:
  1. Macrogenia
  2. Mandibular hyperplasia
  3. Mandibular hypoplasia
  4. Maxillary hyperplasia or asymmetry
  5. Maxillary hypoplasia
  6. Microgenia
  7. Prognathism
  8. Retrognathism

#### **Functional Impairment:**

- Clinical records must document the presence of **ONE** of the following conditions as the result of a facial skeletal discrepancy:
  1. Airway defect
  2. Masticatory malocclusion
  3. Soft tissue discrepancies resulting in functional impairment
  4. Speech impairment secondary to the functional deformity/deficiency



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## **LEFORT I OSTEOTOMY**

- LeFort I osteotomy to correct a functional impairment (as defined above) resulting from a facial skeletal discrepancy (as defined above) are considered **medically necessary** with clinical documentation, radiological report, and preoperative intraoral and facial photographs with **ONE** of the following:
  1. Anterior open bite/no overbite
  2. Maxillary occlusal cant > 4 degrees
    - Orthodontic therapy > 6 months
  3. Vertical maxillary excess and **ALL** of the following:
    - Lip incompetence
    - Ratio of lower face height to total face height > 60%
    - Orthodontic therapy > 6 months
  4. Vertical maxillary deficiency and **ALL** of the following:
    - Malocclusion
    - Ratio of lower face height to total face height < 50%
    - Orthodontic therapy > 6 months
  5. Retrognathic maxilla and **ALL** of the following:
    - Nasolabial angle > 100 degrees
    - Malocclusion
    - Sella-Nasion-A (SNA) decreased for norms
    - Orthodontic therapy > 6 months
  6. Prognathic maxilla and **ALL** of the following:
    - Nasolabial angle < 75 degrees
    - Lip incompetence
    - Sella-Nasion-A (SNA) increased for norms
    - Orthodontic therapy > 6 months

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## LEFORT I OSTEOTOMY

- Lefort I osteotomy for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
  5. Insufficient evidence to support improvement outside the investigational setting

These indications include, *but are not limited to*:

- Intent to enhance or improve appearance
- Absence of a functional physical impairment

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### Resources:

**Literature reviewed 04/05/24. We do not include marketing materials, poster boards and non-published literature in our review.**

1. Bohner L, Lustosa RM, Stamm T, Hanisch M, Kleinheinz J, Jung S. Influence of marginal incision and Le Fort I osteotomy on periodontal tissues: a prospective longitudinal study. *Odontology*. Jan 2023;111(1):201-206. doi:10.1007/s10266-022-00721-9
2. Buchanan EP. Syndromes with craniofacial abnormalities. In: Firth HV, ed. *UpToDate*. UpToDate; 2022. Accessed March 21, 2024. <https://www.uptodate.com/contents/syndromes-with-craniofacial-abnormalities>
3. Cordero-Garcia T, Lozano-Rosado R, Fontillon-Alberdi M, Gutierrez-Perez JL, Infante-Cossio P. Surgical ciliated cyst of the maxilla after orthognathic surgery: A case report. *Exp Ther Med*. Jul 2023;26(1):343. doi:10.3892/etm.2023.12042
4. Ebeling M, Scheurer M, Sakkas A, Wilde F, Schramm A. First-Hand Experience and Result with New Robot-Assisted Laser LeFort-I Osteotomy in Orthognathic Surgery: A Case Report. *J Pers Med*. Feb 3 2023;13(2)doi:10.3390/jpm13020287
5. Isaacson GC. Congenital anomalies of the jaw, mouth, oral cavity, and pharynx. In: Messner AH, ed. *UpToDate*. UpToDate; 2022. Accessed March 21, 2024. <https://www.uptodate.com/contents/congenital-anomalies-of-the-jaw-mouth-oral-cavity-and-pharynx>
6. Jeil Medical Corporation. 510K: The Lefort II System (K150965). U.S. Food and Drug Administration. 2015. Accessed March 22, 2024. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf15/K150965.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf15/K150965.pdf)

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7. Manishaa V, Pendem S, M RM, Pandurangan SM. Evaluation of Postoperative Outcome and Incidence of Complications in Multisegment Le Fort I Osteotomies: A Case Series. *Cureus*. May 2023;15(5):e39772. doi:10.7759/cureus.39772
8. Moorhead A, Serra M. Le Fort Osteotomy. *StatPearls*. StatPearls Publishing Copyright © 2024, StatPearls Publishing LLC.; 2024.
9. Nickel KJ, DeSerres JJ, Louie G. Utility of the LeFort I Osteotomy in the Acute Management of Midface Trauma. *J Craniofac Surg*. Dec 11 2023;doi:10.1097/scs.00000000000009917
10. Passalboni C, Taverne M, Lopez R, Rotenberg M, Lauwers F, Prevost A. Characterization of labiomandibular movements induced after isolated LeFort I osteotomy in the surgical management of class III malocclusion. *PLoS One*. 2023;18(10):e0292391. doi:10.1371/journal.pone.0292391
11. Patil S, Basavaraddi SM, Revankar AV, et al. Comparative Evaluation of Relapse After LeFort 1 Osteotomy in Cleft Palate and Non-cleft Individuals: A Longitudinal Study. *Cureus*. Jan 2024;16(1):e52298. doi:10.7759/cureus.52298
12. Rachmiel A, Capucha T, Ginini JG, Emodi O, Aizenbud D, Shilo D. Treatment of Facial Asymmetry Using Distraction Osteogenesis in a Mandible First Approach. *Plast Reconstr Surg Glob Open*. Sep 2023;11(9):e5255. doi:10.1097/gox.00000000000005255
13. Sabri H, Tehranchi A, Sarkarat F. 3-dimensional analysis of nasal soft tissue alterations following maxillary Lefort I advancement with and without impaction using 3D photogrammetry scanner. *Oral Maxillofac Surg*. Mar 2024;28(1):111-123. doi:10.1007/s10006-022-01121-7
14. Stryker. 510K: MP LeFort I Plates (K171364 ). U.S. Food and Drug Administration. 2017. Accessed March 22, 2024. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf17/K171364.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171364.pdf)
15. Tajmiri G, Sh ME. Effect of the absorption rate of suture material on oral mucosal scar formation: A triple-blind randomized controlled trial. *Heliyon*. Jan 15 2024;10(1):e23054. doi:10.1016/j.heliyon.2023.e23054
16. Verzella AN, Alcon A, Schechter J, Shetye PR, Staffenberg DA, Flores RL. LeFort I Horizontal Osteotomy: Defining the Feasibility of the "High Osteotomy". *Cleft Palate Craniofac J*. Oct 26 2023;10556656231202595. doi:10.1177/10556656231202595

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### **Coding:**

CPT: 21141, 21142, 21143, 21145, 21146, 21147, 21421, 21422, 21423, 61586



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<b><u>History:</u></b>	<b><u>Date:</u></b>	<b><u>Activity:</u></b>
Medical Policy Panel (ad hoc)	04/05/24	Approved guideline
Medical Director (Dr. Raja)	03/27/24	Development

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### **Policy Revisions:**



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## LEFORT I OSTEOTOMY

### 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](mailto: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 nilínígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowolgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 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 thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



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Multi-Language Interpreter Services:

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다.

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.

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.

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.

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。

Farsi:

اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 [تماس حاصل نمایید]

Assyrian:

Blue Cross Blue Shield of Arizona ... 877-475-4799

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku.

Thai: หากคุณ หรือคนทศณกาลงช่วยเหลอมคาถามเกยวกับ Blue Cross Blue Shield of Arizona คุณมสทธจะไดรบความช่วยเหลอมและขอมลในภาษา ของคุณไดโดยไมมคาไชจาย พดคยกลาม โทร 877-475-4799