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Cosmetic Surgery and Procedures

Clinical Policy Bulletins | Medical Clinical Policy Bulletins

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Table Of Contents

Policy History

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07/08/2025
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Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes

Policy

Scope of Policy

This Clinical Policy Bulletin addresses cosmetic surgery and procedures.

Introduction

Aetna plans exclude coverage of cosmetic surgery and procedures that are not medically necessary, but generally provide coverage when the surgery or procedure is needed to improve the functioning of a body part or otherwise medically necessary even if the surgery or procedure also improves or changes the appearance of a portion of the body. Additionally, many Aetna plans specify that certain surgeries are not

considered to be cosmetic (e.g., surgery to correct the result of injury, post-mastectomy breast reconstruction, breast augmentation to treat gender dysphoria, surgery needed to treat certain congenital defects such as cleft lip or cleft palate). Please check benefit plan descriptions for details.

This policy statement supplements plan coverage language by identifying procedures that Aetna considers medically necessary despite cosmetic aspects, and other cosmetic procedures that Aetna considers not medically necessary. Please note that, while this policy statement addresses many common procedures, it does not address all procedures that might be considered to be cosmetic surgery excluded from coverage. Aetna reserves the right to deny coverage for other procedures that are cosmetic and not medically necessary.

I. Medical Necessity

A. *Surgeries and Procedures*

The following surgeries and procedures are considered medically necessary when criteria are met. The requesting physicians may be required to submit documentation, including photographs, letters documenting medical necessity, chart records, etc.

1. Blepharoplasty

   Considered medically necessary when criteria in CPB 0084 - Eyelid Surgery (0084.html), are met;

2. Breast reduction

   Considered medically necessary when criteria in CPB 0017 - Breast Reduction Surgery and Gynecomastia Surgery (0017.html) or CPB 0615 - Gender Affirming Surgery (../600_699/0615.html), are met;

3. Chemical peels (chemical exfoliation)

Considered medically necessary when criteria in CPB 0251 - Dermabrasion, Chemical Peels, and Acne Surgery (../200_299/0251.html) are met;

4. Collagen implant (e.g., Zyderm)

   Considered cosmetic except as a treatment for urinary incontinence when medical necessity criteria in CPB 0223 - Urinary Incontinence (../200_299/0223.html) are met;

5. Dermabrasion

   Considered medically necessary when criteria in CPB 0251 - Dermabrasion, Chemical Peel, and Acne Surgery (../200_299/0251.html) are met;

6. Dermal injections of Food and Drug Administration (FDA)-approved fillers (e.g., poly-L-lactic acid dermal injection (Sculptra) or calcium hydroxylapatite dermal injection (Radiesse) for HIV lipoatrophy)

   Considered medically necessary for treating facial lipodystrophy syndrome due to antiretroviral therapy in HIV-infected persons; considered cosmetic for all other indications;

   Retreatments with FDA-approved fillers are considered medically necessary for facial lipodystrophy syndrome due to antiretroviral therapy in HIV-infected persons;

7. Earlobe repair

   Repair (e.g., tear) of a traumatic injury is considered medically necessary;

   Earlobe repair to close a stretched pierce hole, in the absence of a traumatic injury, is considered cosmetic;

8. Excision or shaving of rhinophyma for the treatment of bleeding or infection refractory to medical therapy (i.e. the

need for repeated cautery of bleeding telangiectasias or frequent courses of antibiotics for pustular eruptions)

Excision or shaving of rhinophyma is considered cosmetic when the afore-mentioned criteria are not met;

9. Keloids

   Repair of keloids is considered medically necessary if they cause pain or a functional limitation;

   Note: For repair of keloids that do not cause pain or functional impairment, exceptions to cosmetic surgery exclusion may apply. Please check benefit plan descriptions. See also CPB 0551 - Radiation Treatment for Selected Nononcologic Indications (../500_599/0551.html);

10. Lip surgery

    Considered medically necessary for neoplasm or trauma;

11. Lipectomy or liposuction and autologous fat grafting

    Considered medically necessary for breast reconstruction according to the medical necessity criteria in CPB 0185 - Breast Reconstructive Surgery (../100_199/0185.html). See also CPB 0615 - Gender Affirming Surgery (../600_699/0615.html);

12. Lipomas

    Excision is considered medically necessary if lipomas are tender and inhibit the member's ability to perform daily activities due to the lipomas' location on body parts that are subject to regular touch or pressure;

13. Otoplasty/Pinnaplasty

    Considered medically necessary when performed to improve hearing by directing sound in the ear canal, whether the ears are absent or deformed from trauma,

surgery, disease, or congenital defect. Otoplasty to correct large or protruding ears is considered cosmetic when the surgery will not improve hearing;

14. Panniculectomy

    Considered medically necessary when criteria are met, as set forth in CPB 0211 - Abdominoplasty, Suction Lipectomy, and Ventral Hernia Repair (../200_299/0211.html);

15. Phalloplasty for transgender (female to male) surgery

    Considered medically necessary when criteria are met, as set forth in CPB 0615 - Gender Affirming Surgery (../600_699/0615.html);

16. Pulsed-dye laser treatment and excision of port wine stains and other hemangiomas

    Considered medically necessary when lesions are located on the face and neck. Also, removal of symptomatic scrotal hemangiomas and symptomatic cavernous hemangiomas is considered medically necessary. See also CPB 0559 - Pulsed Dye Laser Treatment (../500_599/0559.html);

17. Rhinectomy

    Considered medically necessary for neoplasm or frostbite;

18. Rhinoplasty

    Considered medically necessary for indications set forth in CPB 0005 - Septoplasty and Rhinoplasty (0005.html);

19. Rhytidectomy (including meloplasty, face lift)

    Considered medically necessary when there is functional impairment that cannot be corrected without surgery;

20. Scar revision

Repair of scars that result from surgery is considered medically necessary if they cause symptoms or functional impairment. **Note**: Exceptions to cosmetic surgery exclusion may apply to repair of scars that do not cause pain or functional impairment. Please check benefit plan descriptions;

21. Scrotoplasty

    Considered medically necessary for repair of congenital defects affecting the scrotum (e.g., penoscrotal webbing), tissue damage caused by infections and trauma, and gender affirming care. Scrotoplasty is considered cosmetic for all other indications.

22. Septoplasty

    Considered medically necessary when criteria are met, as set forth in CPB 0005 - Septoplasty and Rhinoplasty (0005.html);

23. Skin tag removal

    Considered medically necessary when located in an area of friction with documentation of repeated irritation and bleeding;

24. Tattoo

    Considered medically necessary in conjunction with reconstructive breast surgery post-mastectomy, and for marking for radiation therapy. See CPB 0185 - Breast Reconstructive Surgery (../100_199/0185.html);

25. Umbilectomy

    Considered medically necessary for the management of infected urachal cysts.

26. Ventral hernia repair

Considered medically necessary when criteria are met, as set forth in CPB 0211 - Abdominoplasty, Suction Lipectomy, and Ventral Hernia Repair (../200_299/0211.html).

B. *Implantation and Attachment of Prostheses*

Note: Most Aetna plans cover prosthetic devices that temporarily or permanently replace all or part of an external body part that is lost or impaired as a result of disease, injury or congenital defect. The surgical implantation or attachment of covered prosthetics is covered, regardless of whether the covered prosthetic is functional (i.e., regardless of whether the prosthetic improves or restores a bodily function). The following surgical implantations are covered when medical necessity criteria for the prosthetic device are met, even though the prosthetic device does not correct a functional deficit.

The following prostheses are considered medically necessary when criteria are met:

1. Breast reconstruction - see CPB 0185 - Breast Reconstructive Surgery (../100_199/0185.html);
2. Ear (auricular) prostheses - see CPB 0620 - Facial Prostheses, External (../600_699/0620.html);
3. Eye (ocular) prostheses - see CPB 0619 - Eye Prosthesis (../600_699/0619.html);
4. Facial prosthesis - see CPB 0620 - Facial Prostheses, External (../600_699/0620.html);
5. Hair transplant - considered medically necessary when performed to correct permanent hair loss that is clearly caused by disease or injury; hair transplants performed to correct male pattern baldness or age-related hair thinning in women are considered cosmetic;
6. Testicular prostheses - considered medically necessary for replacement of congenitally absent testes, or testes lost due to disease, injury, or surgery.

II. Experimental, Investigational, or Unproven

The following are considered experimental, investigational, or unproven:

- Removal of injected silicone for prevention or treatment of autoimmune disease, including autoimmune/inflammatory syndrome induced by adjuvants (ASIA) syndrome
- The Renuvion device (previously branded as J-Plasma hand-piece) for use with liposuction.

III. Cosmetic

The following surgeries and procedures are considered cosmetic in nature:

- Aesthetic alteration of the female genitalia (e.g., hymenoplasty, inverted V hoodoplasty, labiaplasty, and mons pubis pexy)
- Aesthetic operations on umbilicus
- Breast augmentation (breast implants and pectoral implants) - for medical necessity criteria for breast reconstruction, see CPB 0185 - Breast Reconstructive Surgery (../100_199/0185.html); see also CPB 0142 - Breast Implant Removal (../100_199/0142.html); for medical necessity criteria for augmentation mammoplasty to treat gender dysphoria, see CPB 0615 - Gender Affirming Surgery (../600_699/0615.html)
- Breast lift (mastopexy)
- Buttock lift or augmentation
- Cheek implant (malar implant/augmentation)
- Chin implant (genioplasty, mentoplasty)
- Collagenase clostridium histolyticum-aaes (Qwo, Endo Aesthetics LLC) injection for treatment of moderate to severe cellulite in the buttocks
- Correction of diastasis recti abdominis (see CPB 0211 - Abdominoplasty, Suction Lipectomy, and Ventral Hernia Repair (../200_299/0211.html))
- Correction of inverted nipple

- DaxibotulinumtoxinA-lanm (Daxxify; Revance Therapeutics, Inc.) injection for treatment of glabellar lines (**Note:** For use in cervical dystonia, see CPB 0113 - Botulinum Toxin (../100_199/0113.html))
- Deoxycholic acid injection (e.g., Kybella)
- Ear or body piercing
- Electrolysis or laser hair removal (Note: for electrolysis for gender dysphoria, see CPB 0615 - Gender Affirming Surgery (../600_699/0615.html))
- Excision of excessive skin of thigh (thigh lift, thighplasty), leg, hip, buttock, arm (arm lift, brachioplasty), fore-arm or hand, submental fat pad, or other areas (see CPB 0211 - Abdominoplasty, Suction Lipectomy, and Ventral Hernia Repair (../200_299/0211.html))
- Eyebrow/eyelash tattooing
- Gynecomastia surgery (see CPB 0017 - Breast Reduction Surgery and Gynecomastia Surgery (0017.html))
- Intense pulsed light laser for facial redness
- Lacrimal gland resuspension for lacrimal gland prolapse
- LetibotulinumtoxinA-wlbg (Letybo; Hugel, Inc.) injection for treatment of glabellar lines
- Mesotherapy (injection of various substances into the tissue beneath the skin to sculpt body contours by lysing subcutaneous fat)
- Neck Tucks
- Removal of frown lines
- Removal of spider angiomata
- Removal of supernumerary nipples (polymastia)
- Salabrasion
- Selective neurectomy of the gastrocnemius muscle for correction of calf hypertrophy
- Surgery for body dysmorphic disorder
- Surgery to correct moon face
- Surgery to correct tuberous breast deformity
- Surgical depigmentation (e.g., laser treatment) of nevus of Ito or Ota
- Tattoo removal
- Treatment with small gel-particle hyaluronic acid (e.g., Restylane) and large gel-particle hyaluronic acid (e.g., Perlane)

to improve the skin's contour and/or reduce depressions due to acne, injury, scars, or wrinkles
- Use of Laviv (azficel-T)
- Vaginal rejuvenation procedures (clitoral reduction, designer vaginoplasty, hymenoplasty, re-virgination, G-spot amplification, pubic liposuction or lift, reduction of labia minora, labia majora surgery/reshaping, thermal therapy [e.g., radiofrequency (ThermiVa and Viveve procedures) and laser] and vaginal tightening, not an all-inclusive list).

IV. Related Policies

- CPB 0005 - Septoplasty and Rhinoplasty (0005.html)
- CPB 0017 - Breast Reduction Surgery and Gynecomastia Surgery (0017.html)
- CPB 0050 - Varicose Veins (0050.html)
- CPB 0084 - Eyelid Surgery (0084.html)
- CPB 0095 - Orthognathic Surgery (0095.html)
- CPB 0113 - Botulinum Toxin (../100_199/0113.html)
- CPB 0142 - Breast Implant Removal (../100_199/0142.html)
- CPB 0185 - Breast Reconstructive Surgery (../100_199/0185.html)
- CPB 0211 - Abdominoplasty, Suction Lipectomy, and Ventral Hernia Repair (../200_299/0211.html)
- CPB 0223 - Urinary Incontinence (../200_299/0223.html)
- CPB 0251 - Dermabrasion, Chemical Peels, and Acne Surgery (../200_299/0251.html)
- CPB 0272 - Pectus Excavatum and Poland's Syndrome: Surgical Correction (../200_299/0272.html)
- CPB 0310 - Thoracoscopic Sympathectomy (../300_399/0310.html)
- CPB 0419 - Graves' Ophthalmopathy Treatments (../400_499/0419.html)
- CPB 0422 - Vitiligo (../400_499/0422.html)
- CPB 0427 - Carbon Dioxide Laser for Actinic Lesions and Other Selected Indications (../400_499/0427.html)
- CPB 0547 - Rosacea (../500_599/0547.html)
- CPB 0551 - Radiation Treatment for Selected Nononcologic Indications (../500_599/0551.html)

- CPB 0559 - Pulsed Dye Laser Treatment (../500_599/0559.html)
- CPB 0566 - Strabismus Repair (../500_599/0566.html)
- CPB 0615 - Gender Affirming Surgery (../600_699/0615.html)
- CPB 0619 - Eye Prosthesis (../600_699/0619.html)
- CPB 0620 - Facial Prostheses, External (../600_699/0620.html)
- CPB 0633 - Benign Skin Lesion Removal (../600_699/0633.html)

Applicable CPT / HCPCS / ICD-10 Codes

CPT codes covered if selection criteria are met:

Code	Code Description
11200	Removal of skin tags, multiple fibrocutaneous tags, any area; up to and including 15 lesions [not covered for more than 15 lesions and billed with +11201]
11300 - 11313	Shaving of epidermal or dermal lesions
11400 -11446	Excision of benign lesions
11920 - 11922	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation [not covered for eyebrow/eyelash tattooing]
11950 - 11954	Subcutaneous injection of filling material (e.g., collagen)
12011	Simple repair of superficial wounds of face, ears, eyelids, nose, lips, and/or mucous membranes; 2.5 cm or less
12051	Layer closure of wounds of face, ears, eyelids, nose, lips, and/or mucous membranes; 2.5 cm or less
15220 - 15221	Full thickness graft, free, including direct closure of donor site, scalp, arms, and/or legs
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate

Code	Code Description
+15772	each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
+15774	each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15780 - 15782	Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis); segmental, face; or regional, other than face
15788 - 15793	Chemical peel
15820 - 15823	Blepharoplasty
15830	Excision, excessive skin and subcutaneous tissue (including lipectomy); abdomen infraumbilical panniculectomy [documentation required] [not covered for aesthetic operations on umbilicus]
15840 - 15845	Graft for facial nerve paralysis
15877	Suction assisted lipectomy; trunk [covered for medically necessary breast reconstruction and hyperhidrosis only]
17106 - 17108	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique)
17360	Chemical exfoliation for acne (e.g., acne paste, acid)
19318 - 19350, 19357 - 19396	Repair and/or reconstruction of breast [except breast lift (mastopexy)] [not covered to repair tuberous breast deformity]
21740 - 21743	Reconstructive repair of pectus excavatum or carinatum
30120	Excision or surgical planing of skin of nose for rhinophyma
30150	Rhinectomy; partial
30160	Rhinectomy; total
30420, 30435, 30450, 30460, 30462	Rhinoplasty

Code	Code Description
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
37785	Ligation, division, and/or excision of varicose vein cluster(s), one leg
40500	Vermilionectomy (lip shave), with mucosal advancement
40510	Excision of lip; transverse wedge excision with primary closure
40520	Excision of lip; V-excision with primary direct linear closure
40525	Excision of lip; full thickness, reconstruction with local flap (eg, Estlander or fan)
40527	Excision of lip; full thickness, reconstruction with cross lip flap (Abbe-Estlander)
40530	Resection of lip, more than one-fourth, without reconstruction
49250	Umbilectomy, omphalectomy, excision of umbilicus (separate procedure)
51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck
54660	Insertion of testicular prosthesis (separate procedure)
55175 – 55180	Scrotoplasty
67901 - 67909	Repair of brow ptosis or blepharoptosis
CPT codes not covered for indications listed in the CPB:	
Thermal therapy (e.g., radiofrequency (ThermiVa and Viveve procedures) and laser), Laviv (azficel-hyphenT) - no specific code:	
0419T	Destruction neurofibroma, extensive, (cutaneous, dermal extending into subcutaneous); face, head and neck, greater than 50 neurofibroma
0420T	trunk and extremities, extensive, greater than 100 neurofibroma
0437T	Implantation of non-biologic or synthetic implant (eg, polypropylene) for fascial reinforcement of the abdominal wall (List separately in addition to code for primary procedure)

Code	Code Description
+ 11201	Removal of skin tags, multiple fibrocutaneous tags, any area; each additional ten lesions (List separately in addition to code for primary procedure)
15775 - 15776	Punch graft for hair transplant
15783	Dermabrasion; superficial, any site (e.g., tattoo removal)
15786 - 15787	Abrasion; single lesion (e.g., keratosis, scar); each additional four lesions or less (List separately in addition to code for primary procedure)
15819	Cervicoplasty
15824 - 15829	Rhytidectomy
15832 - 15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy, thigh, leg, hip, buttock, arm, forearm or hand, submental fat pad, or other area
+ 15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g. abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
15876	Suction assisted lipectomy, head and neck
15878 - 15879	Suction assisted lipectomy; upper and lower extremity
17110	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; up to 14 lesions
17111	15 or more lesions
17380	Electrolysis epilation, each 30 minutes
19120	Excision of cyst, fibroadenoma, or other benign or malignant tumor, aberrant breast tissue, duct lesion, nipple or areolar lesion (except 19300), open, male or female, 1 or more lesions [supernumerary nipples]
19300	Mastectomy for gynecomastia
19316	Mastopexy
19355	Correction of inverted nipples

Code	Code Description
21120 - 21123	Genioplasty
21125 - 21127	Augmentation, mandibular body or angle; prosthetic material or with bone graft, onlay or interpositional (includes obtaining autograft)
21137 - 21139	Reduction forehead
21270	Malar augmentation, prosthetic material
21280	Medial canthopexy (separate procedure)
21282	Lateral canthopexy
26590	Repair macrodactylia, each digit
27326	Neurectomy, popliteal (gastrocnemius)
30400 - 30410	Rhinoplasty, primary
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
31830	Revision of tracheostomy scar
49591	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible
49592	less than 3 cm, incarcerated or strangulated
49593	3 cm to 10 cm, reducible
49594	3 cm to 10 cm, incarcerated or strangulated
49595	greater than 10 cm, reducible
49596	greater than 10 cm, incarcerated or strangulated
49613	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible
49614	less than 3 cm, incarcerated or strangulated
49615	3 cm to 10 cm, reducible
49616	3 cm to 10 cm, incarcerated or strangulated

Code	Code Description
49617	greater than 10 cm, reducible
49618	greater than 10 cm, incarcerated or strangulated
56620	Vulvectomy simple; partial [not covered for cosmetic indications]
56800	Plastic repair of introitus [not covered for cosmetic indications]
56805	Clitoroplasty for intersex state [not covered for cosmetic indications]
56810	Perineoplasty, repair of perineum, nonobstetrical (separate procedure) [not covered for cosmetic indications]
57291 - 57292	Construction of artificial vagina; without or with graft [not covered for cosmetic indications]
57335	Vaginoplasty for intersex state [not covered for cosmetic indications]
69090	Ear piercing
69300	Otoplasty, protruding ear, with or without size reduction
HCPCS codes covered if selection criteria are met:	
D5914	Auricular prosthesis
D5916	Ocular prosthesis
D7995	Synthetic graft - mandible or facial bones, by report
D9914	Administration of dermal fillers
G0429	Dermal filler injection(s) for the treatment of facial lipodystrophy syndrome (LDS) (e.g., as a result of highly active antiretroviral therapy)
L8000 - L8039	Breast prostheses
L8040 - L8049	Nasal, midfacial, orbital, upper facial, hemi-facial, auricular, partial facial, nasal septal, and maxillofacial prostheses
L8600	Implantable breast prosthesis, silicone or equal
L8603	Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies
L8610	Ocular implant
Q2026	Injection, Radiesse, 0.1 ml
Q2028	Injection, sculptra, 0.5 mg

Code	Code Description
Q3031	Collagen skin test
V2623 - V2629	Prosthetic eye
HCPCS codes not covered for indications listed in the CPB:	
Renuvion device, letibotulinumtoxinA-wlbg (Letybo) - no specific code	
C7565	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s) less than 3 cm, reducible with removal of total or near total non-infected mesh or other prosthesis at the time of initial or recurrent anterior abdominal hernia repair or parastomal hernia repair
D5919	Facial prosthesis
D5925	Facial augmentation implant prosthesis
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit
J0591	Injection, deoxycholic acid, 1 mg
J0775	Injection, collagenase, clostridium histolyticum, 0.01 mg
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes
ICD-10 codes covered if selection criteria are met:	
B20	Human immunodeficiency virus [HIV] disease [covered for facial lipodystrophy syndrome due to antiretroviral therapy in HIV-infected persons]
C00.0 - D49.9	Neoplasms [not covered for nevi of Ota and Ito]
E88.1	Lipodystrophy, not elsewhere classified [HIV related]
L57.0	Actinic keratosis
L70.0 - L70.9	Acne
L71.1	Rhinophyma
L74.510 - L74.519	Primary focal hyperhidrosis
L90.8	Other atrophic disorders of skin [wrinkling of skin] [not covered glabellar lines]

Code	Code Description
L91.0	Hypertrophic scar [Keloid scar]
L91.8	Other hypertrophic disorders of the skin [wrinkling of skin][not covered glabellar lines]
N36.8	Other specified disorders of urethra
N39.3 - N39.9	Urinary incontinence
N39.41 - N39.498, R32	Urinary incontinence
N60.11 - N60.19	Diffuse cystic mastopathy
Q16.0 - Q16.9	Congenital malformations of ear causing impairment of hearing
Q36.0 - Q36.9	Cleft lip
Q55.29	Other congenital malformations of testis and scrotum [congenital defects affecting the scrotum (e.g. penscrotal webbing)]
Q64.4	Malformation of urachus [infected urachal cysts]
Q82.5	Congenital non-neoplastic nevus
S01.501A - S01.512S	Unspecified open wound of lip and oral cavity
S01.531A - S01.552S	Puncture wound of lip and oral cavity without foreign body
S01.90xA - S01.95xS	Open wound of unspecified part of head
S02.2xxA - S02.2xxS	Fracture of nasal bones
S09.8xxA - S09.93xS	Other specified injuries of head
T33.011A - T34.99xS	Superficial frostbite and frostbite with tissue necrosis
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status [HIV] infection status [covered for facial lipodystrophy syndrome due to antiretroviral therapy in HIV-infected persons]
Z85.3	Personal history of malignant neoplasm of breast

Code	Code Description
Z90.10 - Z90.13	Acquired absence of breast
ICD-10 codes not covered for indications listed in the CPB:	
F45.22	Body dysmorphic disorder
F52.0 - F52.9 F64.0 - F66	Sexual and gender identity disorders
L68.0 - L68.9	Hirsutism
L90.8	Other atrophic disorders of skin [nasolabial fold wrinkles]
L98.8	Other specified disorders of the skin and subcutaneous tissue [cellulite]
M04.1 - M04.9	Auto inflammatory syndromes
M35.00 - M35.9	Other systemic involvement of connective tissue [autoimmune disease]
M62.08	Separation of muscle (nontraumatic), other site [diastasis recti]
N64.59	Other signs and symptoms in breast [inverted nipple]
N90.60 - N90.69	Hypertrophy of vulva
O92.011 - O92.03	Retracted nipple associated with pregnancy, the puerperium, and lactation
O92.20 - O92.29	Other and unspecified disorders of breast associated with pregnancy and the puerperium [inverted nipple]
Q67.7	Pectus carinatum
Q83.3	Accessory nipple [supernumerary nipple]

Background

Mest and Humble (2009) evaluated the long-term safety, duration of effect, and satisfaction with serial injections of poly-l-lactic acid (PLLA) for HIV-associated facial lipoatrophy. In this single-site, open-label, re-treatment study, 65 HIV-positive patients were treated with injectable

PLLA every 5 weeks (until optimal re-correction). Presenting degree of lipoatrophy based on the James scale (1 = mild, 4 = severe) was reviewed. Skin thickness was measured at fixed points with calipers. Patients completed a post-retreatment satisfaction questionnaire. Nearly 10 % of patients had persistent correction greater than 36 months, based on patient report. Approximately 50 % required 3 or fewer re-treatments to maintain satisfactory correction (determined by patient and physician). Milder facial lipoatrophy (James scale score 1 to 2) on initial presentation required fewer re-treatments and had more sustained correction. Time to first re-treatment varied according to James scale score: 1 (21.4 months) and 4 (13.0 months). The majority of patients required or asked for 4 re-treatments or less over a 24-month period. The mean patient satisfaction score was 4.9 (1 = dissatisfied, 5 = very satisfied) at study end. No serious adverse events were reported. The authors concluded that injectable PLLA is a safe and effective long-term treatment option for HIV-associated lipoatrophy.

The cosmetic surgery exclusion precludes payment for any surgical procedure directed at improving appearance. The condition giving rise to the patient's pre-operative appearance is generally not a consideration. The only exception to the exclusion is surgery for the prompt repair of an accidental injury or for the improvement of a malformed body member which coincidentally serves some cosmetic purpose. Since surgery to correct a condition of "moon face" which developed as a side effect of cortisone therapy does not meet the exception to the exclusion, it is not covered under Medicare (§1862(a)(10) of the Act).

An UpToDate review on “Overview of breast disorders in children and adolescents” (Banikarim and De Silva, 2012) states that “Tuberous breast is a variant of breast development in which the base of the breast is limited and the nipple and areola are overdeveloped. The etiology is unknown. If the breast examination is otherwise normal, the patient may be referred for cosmetic surgery. The available surgical options vary depending on the location of the hypoplastic breast tissue …. Teenagers may seek breast augmentation for reconstructive purposes related to congenital defects (e.g., amastia, severe breast asymmetry, tuberous breast) or for purely aesthetic reasons”.

Food and Drug Administration-approved for the correction of moderate-to-severe facial wrinkles and folds, small gel-particle hyaluronic acid (SGP-HA, Restylane, Medicis Aesthetics, Inc., Scottsdale, AZ) and large gel-particle hyaluronic acid (LGP-HA, Perlane, Medicis Aesthetics, Inc., Scottsdale, AZ) were studied to evaluate their safety for the correction of oral commissures, marionette lines, upper perioral rhytides and naso-labial folds (NLFs). Brandt et al (2011) examined the safety of SGP-HA and LGP-HA in treating facial wrinkles and folds around the mouth; the secondary objective was to evaluate the effectiveness of these products. This open-label, 4-week study at 2 U.S. centers evaluated SGP-HA and LGP-HA in patients who intended to undergo intradermal injection for correction of perioral wrinkles and folds. At screening, a 5-grade Wrinkle Severity Rating Scale (WSRS) was used to evaluate the baseline appearance of bilateral NLFs, and a 6-grade Wrinkle Severity (WS) scale was used to evaluate the appearance of bilateral oral commissures, marionette lines and upper perioral rhytides. To qualify, each patient must have had moderate-to-severe wrinkles at 1 pair of marionette lines and upper perioral rhytides. Each wrinkle was treated to optimal correction with either SGP-HA or LGP-HA at the discretion of the treating investigator. All reported local and systemic adverse events (AEs) were recorded. At 2 weeks after treatment or touch-up, the treating investigator and the patient assessed appearance using the Global Aesthetic Improvement Scale (GAIS). A total of 20 patients with a mean age of 59.6 years (range of 49 to 65) were treated with an average of 5.58 +/- 1.15 ml of HA for the entire perioral area. Treatment areas included NLFs, marionette lines, oral commissures and perioral rhytides; 18 of 20 patients received both SGP-HA and LGP-HA. Product was injected into the mid or deep dermis using primarily linear threading and multiple punctate pools. Patients experienced a total of 66 treatment-emergent AEs (TEAEs); each patient experienced at least 1 TEAE. The reported events in decreasing order of occurrence were bruising, tenderness, swelling, redness, headache and discomfort. Bruising was more common in the NLFs and marionette lines than in the oral commissures and perioral rhytides. Tenderness occurred more often in the perioral rhytides than in the other areas. The maximum intensity of all TEAEs was considered mild. Most TEAEs resolved within 7 days, with an average duration of 4 days. No serious TEAEs occurred during the study; 100 % of GAIS evaluations by both investigators and patients indicated improvement, regardless of filler used or area treated. The

authors concluded that both SGP-HA and LGP-HA were found to be safe and effective for the correction of perioral wrinkles and folds, with few differences among treatment areas. Both investigator and patient GAIS evaluations indicated aesthetic improvement after SGP-HA and LGP-HA treatment in the perioral area.

Cohen et al (2013) systematically reviewed published evidence for aesthetic use of SGP-HA and LGP-HA. Clinical data on anatomic area, level of evidence, patient population, trial design, endpoints, efficacy, and safety were extracted from PubMed. A total of 53 primary clinical reports were analyzed. The highest-quality efficacy evidence was for the NLFs, with 10 randomized, blind, split-face, comparative trials. Several randomized, blind trials supported treatment of the glabella, lips, and hands. Lower-level evidence (from studies with non-randomized, open-label, or retrospective designs) was recorded for the naso-jugal folds (tear troughs), upper eyelids, nose, infra-orbital hollows, oral commissures, marionette lines, perioral rhytides, temples, and cheeks. Common AEs across anatomic areas were pain, bruising, swelling, and redness. Serious AEs were uncommon (8 events in 8 patients of 4,605 total patients) and were considered to be unrelated (7 events) or probably unrelated (1 event) to treatment. The authors concluded that the safety and effectiveness of SGP-HA and LGP-HA are well-established for NLFs; evidence for the glabella, lips, and hands is more limited. Preliminary reports in other anatomic regions suggested effectiveness without major complications.

While products containing a hyaluronic acid gel (e.g., Perlane and Restylane) are available to improve the contours of the skin, the presence of depressions and/or wrinkles is not a functional impairment. Thus, the use of SGP- HA and LGP-HA for improvement of the skin's contour and/or reduce depressions due to acne, injury, scars, or wrinkles is cosmetic.

Aesthetic Alteration of the Female Genitalia

Triana and Robledo (2015) noted that aesthetic surgery of the external genitalia in women encompasses many procedures and may address the labia minora, clitoral hood, labia majora, mons pubis, or vaginal opening. During the initial evaluation, the surgeon should consider all aspects of

the external genitalia to develop an appropriate surgical plan. It may be necessary to perform 2 or more procedures during the same surgical session to achieve the desired aesthetic result. In this continuing medical education (CME) article, these investigators reviewed the literature and summarized the available cosmetic techniques for female external genitalia. Resection of the labia minora has been described in several peer-reviewed reports. They also discussed the procedures and modifications to direct resection, wedge resection, and de-epithelialization of the labia minora. Aesthetic surgery of the clitoral hood may involve straight-line resection, extended wedge resection, or inverted V hoodoplasty. The mons pubis may be treated with mons pubis pexy, wedge resection, or lipo-modeling. The labia majora can be managed with direct resection or lipo-modeling, and hymenoplasty may be performed to correct a wide vaginal opening.

Hunter and associates (2016) stated that aesthetic alteration of the genitalia is increasingly sought by women unhappy with the size, shape, and appearance of their vulva. Although the labia minora are usually the focus of concern, the entire anatomic region -- labia minora, labia majora, clitoral hood, perineum, and mons pubis -- should be evaluated in a pre-operative assessment of women seeking labiaplasty. Labiaplasty is associated with high patient satisfaction and low complication rates. These investigators discussed the 3 basic labia minora reduction techniques -- edge excision, wedge excision, and central de-epithelialization -- as well as their advantages and disadvantages to assist the surgeon in tailoring technique selection to individual genital anatomy and aesthetic desires. The authors presented key points of the pre-operative anatomic evaluation, technique selection, operative risks, peri-operative care, and potential complications for labia minora, labia majora, and clitoral hood alterations, based on a large operative experience. They stated that labiaplasty competency should be part of the skill set of all plastic surgeons.

On July 30, 2018, Food and Drug Administration (FDA) Commissioner Scott Gottlieb stated that “We’ve recently become aware of a growing number of manufacturers marketing “vaginal rejuvenation” devices to women and claiming these procedures will treat conditions and symptoms related to menopause, urinary incontinence or sexual function. The procedures use lasers and other energy-based devices to destroy or

reshape vaginal tissue. These products have serious risks and don't have adequate evidence to support their use for these purposes. We are deeply concerned women are being harmed. As part of our efforts to promote women's health, the FDA has cleared or approved laser and energy-based devices for the treatment of serious conditions like the destruction of abnormal or pre-cancerous cervical or vaginal tissue, as well as condylomas (genital warts). But the safety and effectiveness of these devices hasn't been evaluated or confirmed by the FDA for "vaginal rejuvenation". In addition to the deceptive health claims being made with respect to these uses, the "vaginal rejuvenation" procedures have serious risks. In some cases, these devices are being marketed for this use to women who have completed treatment for breast cancer and are experiencing symptoms caused by early menopause. The deceptive marketing of a dangerous procedure with no proven benefit, including to women who've been treated for cancer, is egregious. In reviewing adverse event reports and published literature, we have found numerous cases of vaginal burns, scarring, pain during sexual intercourse, and recurring or chronic pain. We haven't reviewed or approved these devices for use in such procedures. Thus, the full extent of the risks is unknown. But these reports indicate these procedures can cause serious harm. Today, we're warning women and their healthcare providers that the FDA has serious concerns about the use of these devices to treat gynecological conditions beyond those for which the devices have been approved or cleared. We recently notified seven device manufacturers of our concerns about inappropriate marketing of their devices for "vaginal rejuvenation" procedures. They are: Alma Lasers, BTL Industries, Cynosure, InMode, Sciton, Thermigen and Venus Concept. We requested that the manufacturers address our concerns within 30 days. If our concerns are not addressed, then the FDA will consider what next actions, including potential enforcement actions, are appropriate. This matter has the full attention of our professional staff".

Body Dysmorphic Disorder

Hundscheid and associates (2014) noted that patients suffering from body dysmorphic disorder (BDD) are preoccupied with a slight or imagined defect in appearance. First of all, to review the literature on the prevalence of BDD in cosmetic surgery and thereafter to review the literature on psychiatric co-morbidity and the outcome of surgical

interventions. These investigators based their search strategy on Embase, Medline and PubMed, using the search terms "body dysmorphic disorder", "cosmetic surgery", "prevalence", "comorbidity" and "outcome". The search covered English and Dutch literature published after the introduction of BDD in DSM-III-R and before 1 November, 2013. A study of the relevant articles enabled these investigators to access additional articles mentioned in these texts. The initial search strategy turned out to be too narrow. It was therefore broadened to include "body dysmorphic disorder", "cosmetic surgery", and "prevalence". Eventually these researchers included 23 original articles. In 11 of these the prevalence of BDD varied from 3.2 to 53.6 %; 12 articles on psychiatric co-morbidity revealed predominantly mood and anxiety disorders on axis I and cluster C personality disorders on axis II. Only 2 studies reported on the outcome of cosmetic surgery performed on BDD patients; surgical interventions, however, seemed to result in new preoccupations with the prolongation of psychiatric co-morbidity. The authors concluded that BDD is a common psychiatric disorder that could sometimes lead to cosmetic surgery. Moreover, they stated that pre-operative screening of BDD patients is vital so that efficient psychiatric treatment can be initiated and patients are not subjected to surgical interventions that may be ineffective or even harmful.

Bowyer and colleagues (2016) stated that a high proportion of individuals with BDD undergo cosmetic treatments in an attempt to "fix" perceived defect(s) in their physical appearance. Despite the frequency with which such procedures are sought, few studies have prospectively examined the outcomes of cosmetic procedures in individuals with BDD. These investigators reviewed the literature and discussed the current debate that exists on outcomes of cosmetic treatment for individuals with BDD. An emerging literature suggests the majority of individuals with BDD have poor outcomes after cosmetic interventions; however, based on the current literature, it cannot be fully ruled out that certain individuals with mild BDD and localized appearance concerns may benefit from these interventions. The authors noted that gaps in the current literature were highlighted, alongside recommendations for future research. They stated that carefully conducted longitudinal studies with well-characterized patient populations are needed.

Sweis and co-workers (2017) noted that BDD is an often under-recognized yet severe psychiatric illness. There is limited guidance for plastic surgeons in the U.S. in how to recognize and manage patients with BDD and protect themselves from potential litigation and harm. Therefore, in collaboration with legal counsel, these investigators reminded their profession of the serious nature of patients with BDD, provided warning signs for recognizing BDD, and critically evaluated the validity of informed consent and the legal ramifications of operating on such patients in this country. These investigators performed a literature review to define the psychopathology of BDD and identify cases of patients with BDD who underwent cosmetic surgery resulting in potential threats to the surgeon. They also carried out an additional search of the legal literature in collaboration with legal counsel to identify key cases of patients with BDD attempting litigation following cosmetic surgery procedures. The diagnostic criteria and psychopathology of BDD were presented. Warning signs were highlighted to alert the plastic surgeon to patients at high risk for BDD. Strategies for legal protection include a pre-procedure check-list for patients who were suspected of having a BDD diagnosis. The authors concluded that BDD is prevalent in the cosmetic surgery population. Patients with BDD often have a poor outcome following aesthetic surgery, which can result in a dangerous or even deadly situation for the surgeon. The authors aimed to remind aesthetic plastic surgeons of the psychopathology, severity, and specific risks associated with operating on patients with BDD while suggesting specific protective strategies.

Collagenase Clostridium Histolyticum-aaes (Qwo)

Collagenase clostridium histolyticum-aaes is available as Qwo (Endo Aesthetics LLC) subcutaneous injection. In 2020, Qwo, a combination of bacterial collagenases, was U.S. FDA approved for the treatment of moderate to severe cellulite in the buttocks of adult women. FDA approval was based on two randomized, multicenter, double-blind, placebo-controlled trials which evaluated the safety and efficacy of Qwo for treatment of cellulite in adult women. A dose of 0.84 mg of Qwo per buttock was administered as 12 subcutaneous injections (0.3-mL injection administered as three 0.1-mL aliquots per injection) in each of 2 buttocks for a total dose of 1.68 mg and a total volume of 7.2 mL (3.6 mL per buttock) per treatment visit. There were 3 treatment visits at 21-day

intervals. The primary efficacy endpoint was the proportion of 2-level multi-component responders at Day 71 post randomization. A 2-level multi-component responder was defined as having an improvement of at least 2 levels of cellulite severity from baseline on both the Clinician Reported Photonumeric Cellulite Severity Scale (CR-PCSS) and the Patient Reported Photonumeric Cellulite Severity Scale (PR-PCSS) in the target buttock. Patient satisfaction with the appearance of their cellulite was assessed using a patient reported outcome scale ranging from 0 (extremely dissatisfied) to 6 (extremely satisfied). Reductions in cellulite severity were observed more frequently in the Qwo group compared to the placebo group as measured by the investigator (CR-PCSS) and patient (PR-PCSS) scales at Day 71 (Endo, 2021).

Warnings and precautions include hypersensitivity reactions and injection site bruising. The most common adverse reactions (1 % or more) were related to the injection site (bruising, pain, nodule, pruritus, erythema, discoloration, swelling, and warmth).

Qwo must not be substituted for other injectable collagenase products. Qwo is not indicated for the treatment of Peyronie's disease or Dupuytren’s contracture. For treatment of Peyronie's disease or Dupuytren's contracture, see CPB 0007 - Erectile Dysfunction (0007.html) and CPB 0800 - Dupuytren's Contracture Treatments (../800_899/0800.html).

DaxibotulinumtoxinA-lanm Injection (Daxxify)

DaxibotulinumtoxinA-lanm injection is available at Daxxify (Revance Therapeutics, Inc.). In September 2022, the FDA approved Daxxify injection, an acetylcholine release inhibitor and neuromuscular blocking agent, for the temporary improvement of moderate to severe frown lines (glabellar lines) in adults. FDA approval was based on two randomized, double-blind, multi-center, placebo-controlled clinical trials, Studies GL-1 and GL-2. A total of 405 subjects were randomized and 406 were treated with 40 Units of daxibotulinumtoxinA and 204 subjects were randomized and 203 were treated with an equal volume of placebo. Subjects were excluded if they had eyelid ptosis, deep dermal scarring, excessive dermatochalasis or an inability to lessen glabellar lines by physically spreading them apart. The total dose was delivered in 5 equally divided

intramuscular injections of 8 Units each to specific sites in the glabellar. Subjects were followed for at least 24 weeks after treatment. Efficacy was determined through the assessment by investigators and subjects of frown wrinkle severity at maximum frown using a 4-point scale (0 = none, 1 = mild, 2 = moderate, 3 = severe). The primary efficacy endpoint (treatment success) was defined as achieving a score of 0 or 1 (none or mild) and an improvement of at least 2 points from baseline for both the investigator's and subject's assessments at Week 4. The results found that 74 percent of subjects achieved a greater than two-grade improvement in glabellar lines at week 4 per both investigator and patient assessment. Eight-eight percent achieved greater two-grade improvement at week 4 and 98 percent achieved none or mild wrinkle severity at week 4.

Daxxify is generally safe and well tolerated with no serious treatment-related adverse events reported in the clinical trials and has a safety profile consistent with other currently available neuromodulators in the aesthetics market. The most commonly observed adverse reactions (1% or more) are headache (6%), eyelid ptosis (2%) and facial paresis (1%).

In August 2023, the FDA approved Daxxify for the treatment of cervical dystonia in adults. See CPB 0113 - Botulinum Toxin (../100_199/0113.html) for additional information.

Deoxycholic Acid Injection (e.g., Kybella)

Sykes and associates (2017) noted that deoxycholic acid (DCA; Kybella, Allergan Pharmaceuticals, Irvine, CA) is a novel injectable treatment used for the cosmetic reduction of redundant submental fat. By inducing adipose cell lysis, the soft tissue alteration induces subsequent contour change and sharpening of the cervico-mental angle. The safety and efficacy have been well established in several prospective clinical trials and subsequent FDA approval for this purpose. This has provided an effective and less invasive alternative to surgical liposuction with virtually no recovery time and less overall discomfort. Given its success for use in this context, a logical step would be to extrapolate to other regions of the body where cosmetic deformity is caused by excessive adipose tissue. In this study, the authors proposed potential options for further use in various targeted areas where subcutaneous fat may be amenable to

reduction with DCA injection, understanding that such uses would be off-label and require an understanding of the regional anatomy and possible complications.

Jegasothy (2018) stated that injection lipolysis using DCA is a minimally invasive technique recently approved by the FDA to treat subcutaneous fat in the submental area, by injecting a cytolytic drug into the superficial adipose tissue. It is the first and only FDA-approved injectable treatment for improving the appearance of moderate-to-severe convexity or fullness associated with submental fat in adults. Given the safety and efficacy of DCA injection lipolysis in the submental area, its use for body contouring in other anatomical areas to treat small volume, localized fat deposits should be explored. This technique can be a therapeutic approach for mild excess fat in the pectoralis/underarm/triceps/upper back (collectively called the “bra-line” in women) in carefully selected patients, usually with a BMI of less than 25. This report highlighted the author’s earliest experience with injectable treatment of bra-line fat accumulation in 2 patients and was the 1st U.S. report of DCA lipolysis in this anatomic region. This area is relatively difficult to treat with other modalities but appeared to be responsive to DCA injection. Safety can be ensured by administering DCA only in the subcutaneous fat. Thorough knowledge of the anatomy of underlying structures and skin thickness is essential. Efficacy can be maximized by careful patient selection. This investigator noted that lipolysis with DCA injection administered by trained physicians is a promising approach for treating bra-line fat. It is likely that most patients will need significantly more DCA per injection session. The author stated that large-scale clinical trials are needed to prove the safety and efficacy of this approach.

Sung and colleagues (2019) stated that injectable DCA is currently approved only for treatment of persistent submental fat (SMF). Many cosmetic surgeons use DCA off-label to treat fat tissue in other areas of the body. There is no review summarizing the off-label uses of injectable DCA. These researchers carried out a systematic literature search through PubMed, Cochrane, CINAHL, and Web of Science databases using search terms “ATX-101 OR Kybella OR deoxycholic OR deoxycholate NOT amphotericin NOT bile” in accordance to PRISMA guidelines to identify off-label uses for injectable DCA or ATX-101. A total of 10 pertinent articles were identified for review. Anatomic areas treated

include the face, brassiere line, foot, and gluteo-trochanteric region. Indications included facial contouring, paradoxical adipose hyperplasia, HIV/HAART-associated buccal fat pad lipodystrophy, and reduction of lipomatous tumors. DCA is effective at causing lipolysis and safe with minimal side effects. Most patients treated for cosmetic indications reported high patient satisfaction. The authors concluded that off-label use of injectable DCA showed a similar safety profile, effectiveness, and overall patient satisfaction compared to FDA-approved use for persistent SMF. DCA appeared to be a safe and effective alternative to surgical reduction of unwanted adipose tissue in non-submental areas. Moreover, these researchers stated that larger-scale studies are needed to examine further cosmetic and potential medical applications.

Liu and colleagues (2021) stated that beyond submental fat reduction, injectable DCA has gained popularity in recent years for various minimally invasive lipolysis applications. In a systematic review, these researchers examined the evidence of off-label uses of injectable DCA. Medline, Embase, CINAHL, Web of Science, and CENTRAL were searched. The outcomes measured included applications of DCA, treatment regimen, and its effectiveness. An overall success rate for each condition was calculated based on the improvement defined in the included studies. A total of 11 studies examined the cosmetic use of DCA for excess adipose tissue on various anatomical locations. The outcomes were examined at time-points ranging from 1 to 21 months post-treatment, with overall success rates over 85 %; 8 case reports and series reported the success of using DCA in the treatment of lipomas, xanthelasmas, paradoxical adipose hyperplasia, fibrofatty residue of infantile hemangioma, piezogenic pedal papules, and HIV-associated lipo-hypertrophy. Although the preliminary effectiveness was high, the overall recommendations for off-label uses were weak because of the lack of high-level studies. The authors concluded that the findings of this review emphasized the diversity of injectable DCA as a minimally invasive technique for lipolysis. Moreover, these researchers stated that further high-level studies demonstrating consistent treatment regimens and methods of evaluation are needed to make more definitive recommendations regarding off-label DCA use.

Laviv (Azficel-T)

Laviv (azficel-T) is an autologous cellular product indicated for improvement of the appearance of moderate-to-severe nasolabial fold wrinkles in adults.

Smith and colleagues (2012) noted that changes associated with aging are partly due to loss of collagen and elastin. Treatment with autologous fibroblasts grown in culture (azficel-T) could help correct the appearance of aging by replacing lost dermal constituents. In a multi-center, double-blind, placebo-controlled trial, these researchers examined the safety and effectiveness of autologous fibroblasts in the treatment of naso-labial fold (NLF) wrinkles. Adults with moderate-to-very severe NLF wrinkles were randomized to receive 3 treatments with autologous fibroblasts or placebo at 5-week intervals. Blinded evaluators and subjects evaluated efficacy using a validated wrinkle assessment scale. A total of 372 subjects were enrolled and underwent treatment; 78 % of subjects treated with autologous fibroblast therapy and 48 % of subjects treated with placebo achieved at least a 1-point improvement on the subject assessment at 6 months ($p < 0.001$), and 64 % of subjects treated with autologous fibroblast therapy and 36 % of those treated with placebo showed at least a 1-point improvement evaluator's assessment ($p < 0.001$); AEs were generally mild, and the treatment was well-tolerated. The authors concluded that autologous fibroblast therapy was safe and effective for the treatment of NLF wrinkles. The availability of autologous cell therapy marked the beginning of a new phase in aesthetic therapy.

LetibotulinumtoxinA-wlbg (Letybo)

LetibotulinumtoxinA-wlbg is branded as Letybo (Hugel, Inc.). On February 29, 2024, the FDA approved Letybo, an acetylcholine release inhibitor and a neuromuscular blocking agent, for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients. FDA approval was based on the safety and efficacy results obtained from three clinical trials (BLESS I [NCT02677298], BLESS II [NCT02677805], and BLESS III [NCT03985982]), which included a total of 1,271 patients with moderate to severe glabellar lines (wrinkles between the eyebrows). These trials were conducted at 31 sites in the United States and European Union.

Patients between 18 and 75 years of age received a single intramuscular injection of Letybo or placebo at five sites within the muscles between the eyebrows. The benefit of Letybo was assessed by determining the proportion of patients achieving a score of 0 or 1 (none or mild) and at least a 2-grade improvement of wrinkles between the eyebrows at maximum frown from baseline to Week 4. Improvement of wrinkles between the eyebrows at maximum frown was assessed independently by both the investigator and the patient using the Glabellar Line Scale (GLS). The GLS is a 4-point grading scale (0 = none, 1 = mild, 2 = moderate, 3 = severe).

Labeled warnings and precautions include the following:

- Spread of toxin effects; swallowing and breathing difficulties can lead to death.
- Potency Units of Letybo are not interchangeable with other preparations of botulinum toxin products.
- Potential serious adverse reactions after Letybo injections for unapproved uses.
- Adverse event reports have been received involving the cardiovascular system, some with fatal outcomes.
- Concomitant neuromuscular disorder may exacerbate clinical effects of treatment.
- To be used with caution in patients with compromised respiratory function or dysphagia.

The most common adverse reaction is headache (2%).

Liposuction for the Treatment of Lipedema

Lipedema is a painful disorder in women characterized by abnormal deposition of adipose tissue in the lower extremities leading to circumferential bilateral lower extremity enlargement typically seen extending from the hips to the ankles resulting in edema, pain and bruising; with secondary lymphedema and fibrosis during later stages. The pathogenesis is unknown and no curative treatment is available. Conservative therapy consisting of lymphatic drainage and compression stockings is often recommended, but is only effective against the edema. Some patients showed a short-term improvement when treated in this

way. Combined decongestive therapy (CDT, namely manual lymphatic drainage, compression garments) is the standard of care in most countries. Since the introduction of tumescent technique, liposuction has been used as a surgical therapeutic option.

Rapprich and colleagues (2011) stated that the removal of the increased fat tissue of lipedema has become possible by employing advanced liposuction techniques, which utilize vibrating micro-cannulas under tumescent local anesthesia. These investigators examined the effectiveness of this approach to lipedema. A total of 25 patients were examined before liposuction and 6 months thereafter. The survey included the measurement of the volume of the legs and several parameters of typical pain and discomfort. The parameters were measured using visual analogue scales (VAS, scale 0 to 10). The volume of the leg was reduced by 6.99 %. Pain, as the predominant symptom in lipedema, was significantly reduced from 7.2 ± 2.2 to 2.1 ± 2.1 ($p < 0.001$). Quality of life (QOL) as a measure of the psychological strain caused by lipedema improved from 8.7 ± 1.7 to 3.6 ± 2.5 ($p < 0.001$). Other parameters also showed a significant improvement and the over-all severity score improved in all patients. The authors concluded that liposuction reduced the symptoms of lipedema significantly.

Schmeller and associates (2012) examined the efficacy of liposuction concerning appearance and associated complaints after a long-term period. A total of 164 patients who had undergone conservative therapy over a period of years, were treated by liposuction under tumescent local anesthesia with vibrating micro-cannulas. In a monocentric study, 112 could be re-evaluated with a standardized questionnaire after a mean of 3 years and 8 months (range of 1 year and 1 month to 7 years and 4 months) following the initial surgery and a mean of 2 years and 11 months (8 months to 6 years and 10 months) following the last surgery. All patients showed a distinct reduction of subcutaneous fatty tissue (average of 9,846 ml per person) with improvement of shape and normalization of body proportions. Additionally, they reported either a marked improvement or a complete disappearance of spontaneous pain, sensitivity to pressure, edema, bruising, restriction of movement and cosmetic impairment, resulting in a tremendous increase in QOL; all these complaints were reduced significantly ($p < 0{\cdot}001$). Patients with lipedema stage II and III showed better improvement compared with

patients with stage I. Physical decongestive therapy could be either omitted (22.4 % of cases) or continued to a much lower degree. No serious complications (wound infection rate 1.4 %, bleeding rate 0.3 %) were observed following surgery. The authors concluded that tumescent liposuction was a highly effective treatment for lipedema with good morphological and functional long-term results.

Peled and co-workers (2012) stated that diagnosis of lipedema is often challenging, and patients frequently undergo a variety of unsuccessful therapies before receiving the proper diagnosis and appropriate management. Patients may experience pain and aching in the lower extremity in addition to distress from the cosmetic appearance of their legs and the resistance of the fatty changes to diet and exercise. These researchers reported a case of a patient with lipedema who was treated with suction-assisted lipectomy and use of compression garments, with successful treatment of the lipodystrophy and maintenance of improved aesthetic results at 4-year post-operative follow-up.

Wollina and associates (2014) noted that In advanced stages of lipedema, reduction of adipose tissue is the only available effective treatment. In elderly patients with advanced lipedema, correction of increased skin laxity has to be considered for an optimal outcome. These investigators reported on a tailored combined approach to improve advanced lipedema in elderly women with multiple co-morbidities. Micro-cannular laser-assisted liposuction of the upper legs and knees was performed under tumescent anesthesia. Medial thigh lift and partial lower abdominoplasty with minimal undermining were used to correct skin laxity and prevent intertrigo (intertriginous dermatitis). Post-surgical care with non-elastic flat knitted compression garments and manual lymph drainage were used. These researchers reported on 3 women aged 55 to 77 years with advanced lipedema of the legs and multiple co-morbidities. Using this step-by-step approach, a short operation time and early mobilization were possible. Minor adverse effects were temporary methemoglobinemia after tumescent anesthesia and post-surgical pain. No severe adverse effects were observed; and patient satisfaction was high. The authors concluded that a tailored approach may be useful in advanced lipedema and was applicable even in elderly patients with multiple co-morbidities.

Atiyeh and colleagues (2015) stated that liposuction is the most common cosmetic surgical procedure worldwide. It has evolved from being designed primarily for body contouring to becoming essential adjunct to various other aesthetic procedures, greatly enhancing their outcome. Despite its hard clear differentiation between an aesthetic and therapeutic indication for some pathologic conditions, liposuction has been increasingly used in various disorders as a therapeutic tool or to improve function. In fact, liposuction has ceased to define a specific procedure and has become synonymous to a surgical technique or tool similar to the surgical knife, laser, electrocautery, suture material, or even wound-dressing products. At present, there appeared to be an enormous potential for the application of liposuction in ablative and reconstructive surgery outside the realm of purely aesthetic procedures. These investigators considered the various non-aesthetic applications of liposuction; implications of this new definition of liposuction should induce 3rd-party public payers and insurance carriers to reconsider their remuneration and reimbursement policies.

Dadras and associates (2017) examined the outcome of liposuction used as treatment for lipedema. A total of 25 patients who received 72 liposuction procedures for the treatment of lipedema completed a standardized questionnaire. Lipedema-associated complaints and the need for CDT were assessed for the pre-operative period and during 2 separate post-operative follow-ups using a VAS and a composite CDT score. The mean follow-up times for the 1st post-operative follow-up and the 2nd post-operative follow-up were 16 months and 37 months, respectively. Patients showed significant reductions in spontaneous pain, sensitivity to pressure, feeling of tension, bruising, cosmetic impairment, and general impairment to QOL from the pre-operative period to the 1st post-operative follow-up, and these results remained consistent until the 2nd postoperative follow-up. A comparison of the pre-operative period to the last post-operative follow-up, after 4 patients without full pre-operative CDT were excluded from the analysis, indicated that the need for CDT was reduced significantly. An analysis of the different stages of the disease also indicated that better and more sustainable results could be achieved if patients were treated in earlier stages. The authors concluded that liposuction was effective in the treatment of lipedema and led to an improvement in QOL and a decrease in the need for conservative therapy.

Reich-Schupke and co-workers (2017) noted that the revised guidelines on lipedema were developed under the auspices of and funded by the German Society of Phlebology (DGP). The recommendations were based on a systematic literature search and the consensus of 8 medical societies and working groups. The guidelines contain recommendations with respect to diagnosis and management of lipedema. The diagnosis is established on the basis of medical history and clinical findings. Characteristically, there is a localized, symmetrical increase in subcutaneous adipose tissue in arms and legs that is in marked disproportion to the trunk. Other findings include edema, easy bruising, and increased tenderness. Further diagnostic tests are usually reserved for special cases that require additional work-up. Lipedema is a chronic, progressive disorder marked by the individual variability and unpredictability of its clinical course. Treatment consists of 4 therapeutic mainstays that should be combined as necessary and address current clinical symptoms: complex physical therapy (manual lymphatic drainage, compression therapy, exercise therapy, and skin care), liposuction and plastic surgery, diet, and physical activity, as well as psychotherapy if necessary. Surgical procedures are indicated if, despite thorough conservative treatment, symptoms persist, or if there is progression of clinical findings and/or symptoms. If present, morbid obesity should be therapeutically addressed prior to liposuction.

Halk and Damstra (2017) noted that in 2011, the Dutch Society of Dermatology and Venereology organized a task force to create guidelines on lipedema, using the International Classification of Functioning, Disability and Health of the World Health Organization (WHO). Clinical questions on significant issues in lipedema care were proposed, involving: making the diagnosis of lipedema; clinimetric measurements for early detection and adequate follow-up; and treatment. A systematic review of literature published up to June 2013 was conducted. Based on available evidence and experience of the task force, answers were formed and recommendations were stated. The guidelines defined criteria to make a medical diagnosis of lipedema, a minimum data set of (repeated) clinical measurements that should be used to ensure early detection and an individually outlined follow-up plan, pillars on which conservative treatment should be based and recommendations on surgical therapeutic options. The authors concluded that little consistent information concerning either diagnostics or therapy could be found in the

literature. It is likely that lipedema is frequently misdiagnosed or wrongly diagnosed as only an aesthetic problem and therefore under-treated or mistreated. Treatment is divided into conservative and chirurgic treatment. The only available technique to correct the abnormal adipose tissue is surgery. To ensure early detection and an individually outlined follow-up, the committee advised the use of a minimum data set of (repeated) measurements of waist circumference, circumference of involved limbs, body mass index (BMI) and scoring of the level of daily practice and psychosocial distress. Promotion of a healthy lifestyle with individually adjusted weight control measures, graded activity training programs, edema reduction, and other supportive measures are pillars of conservative therapy. Tumescent liposuction is the treatment of choice for patients with a suitable health profile and/or inadequate response to conservative and supportive measures.

Rey and colleagues (2018) stated that lipedema is a progressive disease; the signs are limited to the lower limbs. Early signs are non-specific, which is why the diagnosis is often ignored. Later, pain and heaviness of lower limbs become predominant. Finally, at an advanced stage, tissue fibrosis is associated with significant edema. At this stage, patients become severely disabled and bedridden. At the early stage, the treatment is conservative. Liposuction is indicated at the onset of pain. Its effectiveness on pain and long-term control has been demonstrated. Finally, late stages require heavy and complex surgeries combining dermo-lipectomy as well as liposuction.

Selective Neurectomy of the Gastrocnemius Muscle for Correction of Calf Hypertrophy

Wang and colleagues (2015) stated that liposuction alone is not always sufficient to correct the shape of the lower leg, and muscle reduction may be necessary. These researchers evaluated the outcomes of a new technique of selective neurectomy of the gastrocnemius muscle to correct calf hypertrophy. Between October 2007 and May 2010, a total of 300 patients underwent neurectomy of the medial and lateral heads of the gastrocnemius muscle at the Department of Cosmetic and Plastic Surgery, the Second People's Hospital of Guangdong Province (Guangzhou, China) to correct the shape of their lower legs. Follow-up data from these 300 patients were analyzed retrospectively. Cosmetic

results were evaluated independently by the surgeon, the patient, and a third party. Pre-operative and post-operative calf circumferences were compared. The Fugl-Meyer motor function assessment was evaluated 3 months after surgery. The average reduction in calf circumference was 3.2 ± 1.2 cm. The Fugl-Meyer scores were normal in all patients both before and 3 months after surgery. A normal calf shape was achieved in all patients; 6 patients complained of fatigue while walking and 4 of scar pigmentation, but in all cases, this resolved within 6 months. Calf asymmetry was observed in only 2 patients. The authors concluded that the findings of this case-series study suggested that neurectomy of the medial and lateral heads of the gastrocnemius muscle may be safe and effective for correcting the shape of the calves. Level of Evidence= V.

Surgical Removal of Silicone

Levy and Emer (2012) stated that various modalities including systemic and intralesional corticosteroids, minocycline, anti-tumor necrosis factor antibodies or surgical removal can be employed to treat silicone granuloma formation.

Park, et al. (2016) reviewed the management of silicone granulomas. The authors stated that a diverse spectrum of therapies has been utilized to treat silicone granulomas and some may resolve spontaneously, but most are excised surgically or given pharmacological therapy with varying success. The authors stated that surgical excision may be employed, but silicone is a permanent filler and is known to migrate to other areas of the body, making complete removal of the injected material impossible. They noted that this may lead to even more disfigurement, making it an unlikely treatment option particularly for facial granulomas.

Lopiccolo et al (2011) reviewed the management of silicone granulomas after soft tissue injection of the buttocks. The authors noted that the treatment of silicone granulomas can be challenging, and a number of modalities have been implemented with varying degrees of success. Surgical excision was attempted in three reported cases. Two of the three resulted in complete resolution. The granulomas involved in both of these cases were well-circumscribed nodular lesions. In the case that did not result in complete resolution, adequate surgical margins could not be achieved because of the unknown extent of the granulomatous reaction.

Eyebrow / Eyelash Tattooing

Yang and colleagues (1989) reported on 2 patients with epithelioid granulomatous inflammation on the eyebrows after undergoing cosmetic eyebrow tattooing. These investigators analyzed the causative elements from biopsy specimens and tattoo inks with X-ray micro-analysis. The authors suggest that granuloma caused by cosmetic eyebrow tattooing was a complication worthy of mention.

Ro and Lee (1991) reported one case of epithelioid granuloma that occurred at the site of a previous cosmetic eyebrow tattooing. A biopsy specimen showed the organized appearance of epithelioid cell granulomas containing little pigment as well as occasional giant cells, primarily of Langhans' type; thus, showing the characteristic features of granulomatous hypersensitivity. With the use of energy dispersive X-ray micro-analysis and inductively coupled plasma spectrometry, the presence of copper, iron, cobalt, and chromium was demonstrated.

Lee and associates (2001) noted that eyebrow and eyelash tattooing are commonly performed procedures that have a very low rate of reported complications. These investigators described 1 case of infra-orbital pigmentation following eyelash tattooing and another of peri-orbital pigmentation following eyebrow tattooing. The authors concluded that although most complications related to eyelash and eyebrow tattooing, including pigment fanning, have been reported by ophthalmologists, pigment fanning was also of concern to dermatologists.

Tehrani and co-workers (2021) stated that eyebrow tattooing is a relatively common cosmetic procedure for middle-aged women; it can hide age-related ptosis. In a prospective, non-randomized, case-controlled study, these researchers examined the peri-ocular soft tissue changes following eyebrow tattooing and its effects on upper eyelid blepharoplasty (UEBL). This trial included 28 subjects, 14 with eyebrow tattooing for at least 5 years and 14 without eyebrow tattooing. Eyebrow ultrasonography was carried out to measure the peri-ocular soft tissue thickness including skin and subcutaneous tissue on the medial and lateral side of the eyebrow. Then, UEBL was carried out with extended eyelid skin incisions; and the excised tissues evaluated histopathologically. The mean age of patients was 50.6 ± 0.6 and 51.2 ±

5.59 years in non-eyebrow tattooing (NET) and eyebrow tattooing (ET) groups, respectively (p = 0.78). In the ET group, soft tissue thickness was 5.90 ± 1.10 and 6.3 ± 0.95 mm on the lateral and medial side of the eyebrow, respectively, which were significantly thicker compared to the NET group (4.68 ± 0.69 and 4.78 ± 0.56 mm, respectively) (p = 0.001). Histopathological findings ranged from edema-congestion to chronic inflammation and dermal fibrosis that were more frequently observed in ET group; however, this difference was statistically significant only for dermal fibrosis (p = 0.02). Surgical wound complications were observed in 3 patients in the ET group (p = 0.22). The authors concluded that subjects with eyebrow tattooing, as compared to a control group, showed a thicker eyebrow skin on ultrasonography and higher upper eyelid dermal fibrosis on histopathological examination.

The Renuvion Device (Previously Branded as J-Plasma) for Liposuction

Doolabh (2019) noted that although tumescent liposuction provides debulking of body areas with excess subcutaneous fat and concurrent skin laxity, the ability to shrink and re-drape the skin and soft tissue for added definition has remained an elusive goal. Many modalities employed to facilitate fat removal utilizing light energy, ultrasonic (US) energy, or radiofrequency (RF) energy have provided modest skin shrinkage. Apyx Medical's (formerly Bovie Medical) Renuvion (previously branded as J-Plasma) has FDA clearance for the cutting, coagulation, and ablation of soft tissue. In a retrospective, single-center, chart review, the author collected safety and procedural information for patients who have previously undergone liposuction with which Renuvion was used as a tool for sub-dermal coagulation. All procedures occurred before August 2018. A total of 32 patients were identified (3 male and 29 female). The mean follow-up was 6 months (range of 3 to 8 months). None of the patients required a revision or secondary procedure suggesting 100 % of patients had acceptable final outcomes. No device-related AEs or complications were noted, suggesting that within this dataset, Renuvion's unique cool helium plasma technology could be safely used for skin contraction with or without tumescent liposuction or supplemental modalities used to facilitate fat removal that may otherwise contribute to the skin contraction. Moreover, these investigators stated that this review

provided clinically relevant data, served as a framework for future prospective studies including formal assessment of patient satisfaction, and guided the development and applications of this unique technology.

The authors stated that as with all retrospective chart reviews, limitations exist in the data collection. These included use of a single-site, small sample size (n = 32), collection of variables not routinely captured in the patients' records (e.g., separation of lipoaspirate volumes of fat from tumescence), and depth of the passes was not quantified.

The FDA provided an update (February 27, 2023) on the use of Renuvion/J-Plasma device for certain aesthetic procedures: "Today, we are informing consumers and health care providers about a Renuvion/J-Plasma handpiece that can be used under the skin in certain procedures intended to improve the appearance of loose skin. On July 15, 2022, the FDA cleared the Renuvion APR Handpiece for use in subcutaneous dermatological and aesthetic procedures to improve the appearance of lax (loose) skin in the neck and submental (under the chin) region. The labeling and training for the Renuvion APR Handpiece will include updated instructions for device power settings and treatment parameters specific to use in procedures under the skin for the neck and chin regions. It is important to note that use of the Renuvion APR Handpiece has not been cleared or approved for use in any other aesthetic skin procedure, or in combination with liposuction. The FDA will continue to monitor reports of adverse events with use of Renuvion/J-Plasma for aesthetic skin procedures".

Umbilectomy for the Management of Infected Urachal Cysts

Castillo et al (2007) stated that anomalies of the urachal remnant are rare. Urachal cysts are usually asymptomatic; however, when they become infected, they can mimic a wide variety of intra-abdominal pathologies. These investigators presented the cases of 2 patients in which a urachal cyst was found. Two men aged 25 and 38 years, respectively, underwent laparoscopic resection of a urachal remnant. In 1 of the cases the urachal remnant was complicated by infection. Opportune clinical and radiologic diagnose was made in both cases and complete excision of the urachal remnant was performed by laparoscopic means. The procedures were carried out without complications and

follow-up showed excellent results. Both patients presented very short convalescence with rapid recovery. The authors concluded that the treatment of choice for urachal pathology was the complete excision of the complicated lesion. For this matter laparoscopic surgery assured surgical results comparable to conventional surgery adding the advantages of a minimally invasive approach.

In a case-reports study and a literature review, Chiarenza et al (2009) examined the role of laparoscopic excision for the management of urachal remnants. In a 5-year period, a total of 3 children were diagnosed with urachal anomalies presenting as abdominal or urinary symptoms; and were treated by laparoscopic surgery. The average age was 8.3 years (range of 4 to 13),and there were 2 girls and 1 boy. Mean operative time was 90 mins (range of 60 to 120), and there were no post-operative complications. The 3 patients were all discharged by post-operative day 4. The authors concluded that laparoscopy was a safe and effective minimally invasive technique in the management of pediatric urachal anomalies. It was effective even in cases of infected urachal cysts.

Bertozzi et al (2014) examined laparoscopic treatment of symptomatic urachal remnants in children. These investigators reviewed their experience analyzing different approaches and results obtained in an 8-year period. From July 2005 to September 2013, a total of 12 children underwent 13 interventions for the treatment of symptomatic urachal remnants. In 4 patients, the technique was a laparoscopic-assisted removal of the remnant, in 2 patients, a laparoscopic-assisted drainage of a urachal abscess, and in 7 patients, a laparoscopic excision of the remnant; 1 patient underwent a double intervention -- laparoscopic drainage of an infected urachal remnant and its delayed laparoscopic excision. The laparoscopic-assisted removal of the urachal remnant was carried out in 2 cases of infected urachal sinus, in 1 case of symptomatic sinus, and in 1 case of infected urachal cyst. The laparoscopic-assisted drainage of urachal abscesses was performed in 2 patients: In 1 patient, the abscess was because of an infected sinus while in the other patient, the abscess was caused by an infected cyst. Of the 7 patients treated with pure laparoscopic technique, 1 had a symptomatic sinus, another had an association between a symptomatic urachal sinus and a urachal cyst, and 5 patients had a symptomatic urachal cyst. In all cases, intra-

operative or post-operative complications and recurrences did not occur, and the cosmetic results were good. Follow-up ranged from 6 months to 8 years and 8 months. The authors concluded that laparoscopic surgery for symptomatic urachal remnants was safe and reliable in cases of drainage of urachal abscess and in cases of excision of the remnant. Laparoscopy allowed a radical excision of the remnants with all the advantages of this procedure. In case of conversion, laparoscopic-assisted technique with minimal incision could be a good alternative to open surgery.

Heuga et al (2015) noted that the classical management of urachal remnants consists of surgical resection to prevent infections and long-term malignancies; however, some reports have recently spread a wait and see management. In a retrospective, single-center study, these investigators reported the results of the surgical management in their institution. They reviewed the findings of all patients managed for urachal remnants from January 2005 to December 2014. A total of 35 patients have been operated during the study period (18 girls and 17 boys). Mean age at surgery was 4.9 ± 4.4 years old; 27 patients were referred due to symptoms whereas 8 were discovered incidentally (4 by ultrasound [US] scan and 4 during laparoscopy). Among them, 10 were urachal cysts, 15 were urachus sinusa and 10 were patent urachus; 30 were operated using an open approach and 5 using a laparoscopic approach. Mean length of stay (LOS) was 3.8 ± 1.7 days (1 to 10) with a mean duration of bladder drainage of 2.5 ± 1 days. No major complications occurred. No abnormal tissue was discovered at the histological analysis. The authors concluded that presentation of urachal remnants was variable but surgical outcomes remain excellent in the authors' experience. When symptoms occur, the surgical decision was easy; however, when the diagnosis was incidental, the decision was much more complicated. Official guidelines could ease the decision process and the management of urachal anomalies.

In a retrospective, observational, single-center study, Sui et al (2023) examined the extra-peritoneal laparoscopic urachal mass excision technique and its safety and effectiveness in the treatment of urachal mass. Baseline characteristics were collected from patients who underwent surgery to diagnose a urachal cyst or abscess in the authors' hospital between January 2020 and August 2021. The full-length of the

urachus and part of the top bladder wall were completely removed via the extra-peritoneal approach. Patient outcomes were collected to examine surgical safety and effectiveness, including operation time, intra-operative blood loss, drainage tube removal time, length of stay (LOS), and post-operative complications. All 20 surgeries were successfully performed laparoscopically, and no case was converted to open surgery. The mean body mass index (BMI) of the patients was 24.6 ± 2.2. The mean patient age was 49.3 ± 8.7 years. The mean size of the cysts was 3.0 ± 0.4 cm. The mean operation time was 56.3 ± 12.0 mins. The mean intra-operative blood loss was 28.0 ± 6.4 ml. The mean drainage tube removal time was 3.0 ± 0.5 days. The mean LOS was 5.2 ± 0.4 days. The mean follow-up was 13.4 ± 2.1 months. No post-operative complications were observed during the follow-up period. The short-term follow-up and small patient cohort limited the outcome evaluation. The authors concluded that these findings indicated that the extra-peritoneal laparoscopic approach was a safe and effective method for the treatment of urachal mass. Moreover, these investigators stated that given the drawbacks of the study, further multiple and larger sample-sized trials are needed to confirm these findings.

Furthermore, an UpToDate review on “Care of the umbilicus and management of umbilical disorders” (Palazzi and Brandt, 2023) states that “Surgical excision is performed for all symptomatic omphalomesenteric duct remnants, or remnants such as fibrous bands or cysts that place the patient at risk for bowel obstruction … Surgical excision is required for removal of ectopic tissue in the umbilicus … Surgical excision has been the treatment of choice (for urachal anomalies)”.

Scrotoplasty

McLeod and Alpert (2014) stated that penoscrotal webbing (PSW) is a common reason for deferral of neonatal circumcision. Reports of successful procedures and outcomes in the literature are sparse. These researchers have carried out double-V scrotoplasty (DVS), a modification of a V-Y technique, in 138 patients with excellent results. They retrospectively reviewed the charts of boys who had undergone DVS for PSW since January 2009 by a single surgeon (S.A.A.). The indications, intra-operative findings, concomitant procedures, outcomes, and

complications were recorded. A total of 138 DVSs were performed. Concomitant genital surgeries included 81 hidden penis repairs and 10 other (hernia, hypospadias, chordee, orchidopexy). The median age at the time of surgery was 9.6 months (6.1 months to 9.8 years). Patients were evaluated about 1 month post-operatively. In 7 cases (5 %), minor skin separation occurred at the penoscrotal junction but all healed completely. Superficial skin infection occurred in 1 patient. None required re-operation and cosmetic results were subjectively excellent. The authors concluded that PSW has been corrected in 138 patients without significant complications and with excellent results. This was the largest known peer-reviewed series examining a surgical technique for congenital PSW repair. These investigators believed their technique was simple, reproducible, and, with no diverging suture lines lateral to the median raphe, improves cosmesis.

Stojanovic et al (2021) noted that metoidioplasty is a variant of the gender affirmation technique neo-phalloplasty, where a hormonally enlarged clitoris is reconstructed to become a small penis. The objectives of metoidioplasty are male appearance of the genitalia, voiding in standing position, and completely preserved erogenous sensation of the neo-phallus. However, it does not enable penetrative sexual intercourse due to the small dimensions of the neo-phallus. Basic principles of metoidioplasty were established 50 years ago, and many refinements of the technique have been reported since. The latest improvements were based on the advances in urethroplasty, peri-operative care, as well as new insights into female genital anatomy. The current metoidioplasty technique is a 1-stage procedure that entails vaginectomy, straightening and lengthening of the clitoris, urethral reconstruction by combined flaps and grafts, and scrotoplasty with insertion of testicular implants. Good aesthetic, functional, and - outcomes were attained with this type of neo-phalloplasty.

Miller et al (2021) stated that labia majora, the embryologic homologs of the scrotum, are ideal donor tissue for transgender scrotoplasty. In a retrospective study, these investigators discussed the technique, and surgical outcomes were assessed for scrotoplasty using labia majora rotational advancement flaps. They reviewed the outcomes of phalloplasty patients who underwent either primary or secondary labia majora flap scrotoplasty and perineal reconstruction from October 1, 2017

to December 1, 2019. Bilateral elevation and rotational flap advancement from the posterior to anterior position formed a pouch-like scrotum. Perineal reconstruction entailed multi-layered closure with apposition of the inner thigh skin. The mean follow-up was 12.5 months (0.5 to 26 months). A total of 147 scrotoplasties were carried out. Of the 147 total scrotoplasty patients, 133 had labia majora flap scrotoplasty and perineal reconstruction with single-stage phalloplasty. Distal flap necrosis occurred in 6 patients (4.1 %); 5 were ipsilateral to the groin dissection required for phalloplasty. Large (greater than 1 cm in diameter) perineo-scrotal junction dehiscence occurred in 7 patients (4.7 %). All wounds were managed conservatively except for 3 patients who developed urethra-cutaneous fistulas at the perineo-scrotal junction. All 3 patients required fistula repair; 2 (1.4 %) scrotal hematomas and 3 (2.0 %) perineal hematomas were observed; all required operative intervention. The authors concluded that labia majora flap scrotoplasty via the bilateral rotational advancement technique and perineal reconstruction could be safely carried out during phalloplasty. Minor wound complications were common and often healed with conservative management. Wounds that did not heal may be associated with urethral complications. Hematomas were rare but usually required surgical intervention.

Fascelli et al (2023) noted that transgender and gender diverse (TGD) individuals may seek gender-affirming phalloplasty with specific functional objectives, including erectile function sufficient for penetrative sexual intercourse. Individuals seeking penile prosthesis placement must accept the potential risks to their phallic anatomy. These investigators examined current practices at their center and conducted narrative review of literature discussing techniques for penile prosthesis and testicular prosthesis placement after phalloplasty and scrotoplasty, as well as surgical outcomes, and QOL outcomes where available. Early discussion of a staged approach to phallic construction with a last step of implant placement is important during initial phalloplasty counseling. Pre-operative counseling at the authors' multi-disciplinary center includes: discussion of surgical history, complications, goals and priorities; physical examination to assess phallic size and position, scrotal size, as well as other anatomic findings that may influence prosthesis selection; urinary evaluation, including uroflowmetry with post-void residual (PVR), and a cystoscopy with retrograde urethrogram if indicated based on symptoms or urinary studies, and discussion of surgical risks, benefits and

alternatives. Although none of the commercially available penile prosthesis devices in the U.S. is designed for phalloplasty, modern inflatable and malleable prostheses are adapted for use in the post-phalloplasty setting. Due to the lack of native corpora cavernosa, highly variable phallic anatomy, and the need to adapt implants designed for natal penile anatomy, complication rates of prosthesis placement after phalloplasty remain high, with reported ranges of complications from 20 % to 80 %.

The authors concluded that major complications requiring surgical revision are common relative to implant placement in natal penile anatomy, and include: infection requiring explantation, device extrusion, erosion, migration or malposition, inadequate rigidity, poor aesthetic result, pain, decrease or loss of erogenous and/or tactile sensation, device failure, injury to the urethra, and injury to the neurovascular supply of the penis with resultant partial or complete flap loss. This broad range of complication rates represented the variability with which results were reported and reflected a lack of clear reporting guidelines, significant variability in techniques, and need for more standardization. To optimize outcomes, it is important that surgeons have an in-depth understanding of phalloplasty anatomy and are equipped to manage potential complications in the short- and long-term.

Saxena et al (2023) stated that while masculinizing gender-affirming genital surgeries may include scrotoplasty, there has been limited research on the safety and outcomes of scrotoplasty among transgender men. These researchers compared scrotoplasty complication rates between cisgender and transgender patients using data from the American College of Surgeon's National Surgical Quality Improvement Program (NSQIP) data-base. Data were queried between 2013 and 2019 for all patients with procedure codes for scrotoplasty. Transgender patients were identified via a gender dysphoria diagnosis code; t-tests and Fisher's exact test were employed to identify any differences in demographics, operative characteristics, and outcomes. The primary outcomes of interest were demographic factors, operative details, and surgical outcomes. A total of 234 patients were identified between 2013 and 2019 – 50 were transgender and 184 were cisgender. Age and BMI were significantly different between the 2 cohorts, such that the cisgender cohort was older (M trans = 38 years (SD:14), M cis = 53 years (SD: 15))

and had higher BMI than the transgender cohort (M trans = 26.9 (SD: 5.5), M cis = 35.2 (SD: 11.2)). Cisgender patients also had poorer overall health (p = 0.001), and were more likely to have hypertension (p = 0.001) and diabetes (p = 0.001). Race and ethnicity did not vary significantly between the 2 cohorts. Operative details differed significantly between cohorts, such that transgender patients had a longer operating time (M trans = 303 mins (SD: 155), M cis = 147 mins (SD: 107)) and fewer transgender patients had a simple scrotoplasty (p = 0.02). The majority of gender-affirming scrotoplasties were carried out by plastic surgeons (62 %) whereas the majority of cisgender scrotoplasties were carried out by urologists (76 %). Despite these demographic and pre-operative differences, the number of patients who underwent complex scrotoplasty experiencing any of the tested complications did not differ by gender. The authors concluded that these findings supported scrotoplasty as a safe procedure for transgender patients, with no significant differences in outcomes between transgender and cisgender patients.

Everett et al (2024) presented their technique for 2nd-stage scrotoplasty with autologous tissue augmentation following gender-affirming metoidioplasty. This technique augments the scrotum while removing the upper labia majora and making the penis more visible and accessible. This procedure avoids the need for testicular prostheses and their potential for discomfort, displacement, extrusion, or infection. The preliminary results show ed that the complication rate was low.

Elrouby (2024) noted that the PSW may be congenital or acquired following excessive ventral skin removal during circumcision. Several surgical techniques were described for the treatment of congenital webbed penis without a clear comparison between their outcomes. In a prospective study, these investigators compared the surgical results of Z-scrotoplasty and Heineke-Mikulicz scrotoplasty in the treatment of congenital webbed penis in uncircumcised pediatric patients. This trial included 40 uncircumcised patients who were divided randomly into 2 groups: Group A included 20 patients who were treated by Z-scrotoplasty; and Group B included the other 20 patients who were treated by Heineke-Mikulicz scrotoplasty. All patients were circumcised at the end of the procedure. The age at operation ranged between 6 months and 6 years with an average of 29.9 ± 17.45 months. The authors concluded that treatment of congenital PSW in the pediatric age group could be done

with either Z-scrotoplasty or Heineke-Mikulicz scrotoplasty with satisfactory results; however, without significant difference in the surgical outcomes.

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