Nasolacrimal Duct Obstruction: Treatments

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers balloon dacryocystoplasty (also referred to as balloon dacryoplasty) medically necessary for the treatment of any of the following indications:

1. A mucocele of the lacrimal sac, or
2. Chronic dacryocystitis or conjunctivitis due to lacrimal sac obstruction, or
3. Congenital nasolacrimal duct obstruction that cannot be cured by probing (members should be over 1 year of age), or
4. Epiphora (excessive tearing) due to acquired obstruction within the nasolacrimal sac and duct, or
5. Lacrimal sac infection that must be relieved before intra-ocular surgery.

Aetna considers balloon dacryocystoplasty experimental and investigational for all other indications, including treatment of nasolacrimal duct obstruction associated with the following conditions for which balloon dacryocystoplasty has not been proven to be effective because of insufficient evidence in the peer-reviewed literature:
- Anatomic malformations in the lacrimal duct or bony lacrimal canal
- Dacryocystolithiasis
- Recurrent episodes of active dacryocystitis
- Sarcoidosis
- Tumor (e.g., carcinoma, papilloma) of the lacrimal sac
- Wegener granulomatosis
- Other specific, acquired nasolacrimal sac and duct obstructions (e.g., post-traumatic obstruction of the bony canal).

Aetna considers osteopathic manipulation experimental and investigational for the treatment of congenital nasolacrimal duct obstruction because its effectiveness for this indication has not been established.

Aetna considers the use of silicone stenting in balloon dacryocystoplasty experimental and investigational because of insufficient evidence of this approach.

Aetna considers dacryocystorhinostomy (including transcanalicular laser-assisted dacryocystorhinostomy) medically necessary for persons with nasolacrimal duct obstruction with persistent symptoms despite nasolacrimal duct probing.

**Background**

Twenty percent of infants develop symptoms of congenital nasolacrimal duct obstruction (CNDO) during their 1st month of life, with spontaneous resolution of symptoms being the most common outcome. In the absence of therapy, approximately 1% of infants will still be affected by their 1st birthday. Congenital nasolacrimal duct obstruction is usually caused by a persistent membranous obstruction at the lower end of the nasolacrimal duct, and can often lead to dacryocystitis. Symptoms include epiphora (tearing) and discharge of mucus and pus. Conservative treatments of CNDO include simple lid cleaning and when there is clinical evidence of infection, appropriate antibiotics. The role of lacrimal sac massage in the management of CNDO needs to be further investigated. Probing of the nasolacrimal duct is not usually recommended before the infant is 12 months of age. If
probing fails, other approaches such as turbinate fracture, intubation and balloon dilation of the nasolacrimal duct (dacryocystoplasty/dacryoplasty) may be needed.

Dacryocystoplasty, a non-surgical treatment, is performed as an outpatient procedure after topical anesthesia. It entails the passage of a fluoroscopically guided wire through the lacrimal duct (LacriCATH Lacrimal Duct Balloon Catheter, Atrion Medical Products, Birmingham, AL), followed by balloon dilation at the site of obstruction. If unsuccessful, this procedure still allows a dacryocystorhinostomy to be employed later. Available scientific literature has demonstrated that balloon dacryocystoplasty is effective in treating CNDO.

Adults, especially individuals over 40 years of age, as well as children can also suffer from nasolacrimal duct obstruction(s) that may result in dacryocystitis. For chronic dacryocystitis, symptoms include chronic tearing and discharge, infection, pain and discomfort around the eye. Although the standard method for treating obstruction of lacrimal duct in adults is dacryocystorhinostomy, balloon dacryocystoplasty has been used increasingly for this purpose. Studies have indicated that balloon dilation of the nasolacrimal duct is effective in treating this condition.

In a systematic review, Posadzki et al (2013) evaluate the effectiveness of osteopathic manipulative treatment (OMT) as a treatment of pediatric conditions. A total of 11 databases were searched from their respective inceptions to November 2012. Only randomized clinical trials (RCTs) were included, if they tested OMT against any type of control in pediatric patients. Study quality was critically appraised by using the Cochrane criteria. A total of 17 trials met the inclusion criteria; 5 RCTs were of high methodological quality. Of those, 1 favored OMT, whereas 4 revealed no effect compared with various control interventions. Replications by independent researchers were available for 2 conditions only, and both failed to confirm the findings of the previous studies. Seven RCTs suggested that OMT leads to a significantly greater reduction in the symptoms of asthma, congenital nasolacrimal duct obstruction (post-
treatment), daily weight gain and length of hospital stay, dysfunctional voiding, infantile colic, otitis media, or postural asymmetry compared with various control interventions. Seven RCTs indicated that OMT had no effect on the symptoms of asthma, cerebral palsy, idiopathic scoliosis, obstructive apnea, otitis media, or temporomandibular disorders compared with various control interventions. Three RCTs did not perform between-group comparisons. The majority of the included RCTs did not report the incidence rates of adverse effects. The authors concluded that the evidence of the effectiveness of OMT for pediatric conditions remains unproven due to the paucity and low methodological quality of the primary studies.

Furthermore, an UpToDate review on “Nasolacrimal duct obstruction (dacryostenosis) in children” (Paysse et al, 2014) does not mention the use of OMT as a therapeutic option.

Huang et al (2014) noted that dacryocystorhinostomy (DCR) is commonly performed for epiphora, dacryocystitis and during tumor surgery. External (EXT-DCR) and endoscopic DCR (END-DCR) are both practiced. END-DCR was initially performed with laser (EL-DCR) but has shifted to careful bone removal with mechanical drills (EM-DCR). High level evidence from comparative cohorts was sought to compare outcomes. Medline (1966 to January 28, 2013) and Embase (1980 to January 28, 2013) were searched for comparative studies (RCT/cohorts) of END-DCR to EXT-DCR for acquired nasolacrimal duct (NLD) obstruction. Primary outcome was DCR success, defined as resolution of symptoms and/or patent NLD on irrigation or dacrosintigraphy. Secondary outcomes were scarring, infection and post-operative bleeding. Meta-analysis was performed with the Mantel-Haenszel Method and presented as risk ratios (RR) with confidence intervals (CI). The search identified 3,582 studies and 355 were reviewed after screening. Full text review yielded 19 studies (4 RCTs and 15 cohorts). Overall, EXT-DCR had slightly better success rates than END-DCR (RR 0.96, CI: 0.93 to 1.00). However, EM-DCR outcomes were comparable to EXT-DCR (RR 1.02, CI: 0.98 to 1.06), whereas EL-DCR had poorer outcomes (RR 0.85, CI: 0.79 to 0.91) when compared separately. The RR for scarring, bleeding and infection with END-DCR versus EXT-DCR
was 0.07 (CI: 0.02 to 0.22), 0.72 (CI: 0.46 to 1.13) and 0.24 (CI: 0.11 to 0.54), respectively. The rates of reported revision surgery were similar. The authors concluded that DCR is a procedure with high success rates. Endoscopic procedures differ greatly by technique with EM-DCR offering comparable results to EXT-DCR, without the risk of cosmetically unacceptable scars.

Silicone Stenting in Balloon Dacryocystoplasty:

Marcet et al (2014) reviewed the current surgical practices in endoscopic endonasal DCR (EN-DCR) from the studies of last 12 months. Success rates in EN-DCR now rival those of the conventional external approach. Indications are expanding beyond primary acquired nasolacrimal duct obstruction to include DCR revisions, acute lacrimal sac abscesses, nasolacrimal duct obstructions in patients who have received chemotherapy or radiation, and common canalicular obstructions. There is limited evidence that intubation with silicone stents improves the outcomes. Mitomycin C appears to improve the success rates of EN-DCR, especially revision surgery. Concomitant procedures, such as septoplasty and anterior middle turbinectomy, are sometimes needed in primary as well as revision EN-DCR to achieve high success rates. There is increasing evidence that silicone stents are of limited benefit, whereas mucosal flap formation has been of benefit in case series. The authors concluded that with innovations and improvements in the endonasal approach, EN-DCR has become a viable alternative to external DCR for primary acquired nasolacrimal duct obstruction; EN-DCR has the distinct advantages of no surface scar and a lack of damage to the pump mechanism that often occur with external DCR. They stated that recent evidence indicated a comparable success rate to external DCR.

Feng et al (2011) examined possible differences in success rates of primary DCR with and without silicone intubation, and to find out whether the use of silicone tubes is beneficial. A literature search was conducted in the PubMed, EMBASE, and Cochrane Controlled Trials Register to identify potentially relevant controlled trials. Language was restricted to English. The surgical techniques were categorized into EXT-DCR, endonasal laser-
assisted DCR (LA-DCR), and non-laser EN-DCR. The main outcome measure was success rates after DCR-with and DCR-without silicone intubation. The statistical analysis was carried out using a RevMan 5.0 software. Of 188 retrieved trials from the electronic database, 9 trials (5 RCTs and 4 cohort studies) involving 514 cases met the inclusion criteria. There was no statistically significant heterogeneity between the studies. The pooled RR was 0.99, with a 95 % CI: 0.91 to 1.08. There was no significant difference in the success rates between the DCR with and without silicone intubation (p = 0.81). Sensitivity analysis and subgroups analyses suggested that the result was comparatively reliable. The authors concluded that based on this meta-analysis that included 5 RCTs and 4 cohort studies, no benefit was found for silicone tube intubation in primary DCR. They stated that further well-organized, prospective, randomized studies involving larger patient numbers are needed.

In a prospective randomized study, Al-Qahtani (2012) compared the success rate between the use of silicone stent and no use of silicone stent in endoscopic DCR. Patients were allocated randomly for endoscopic DCR with or without stent. The data collection included age, sex, diagnosis, method, and duration of surgery. Patients were followed-up post-operatively at 1 week, 1 month, and then every 3 months for 1 year. During the period of the study a total of 173 cases of post-saccal stenosis underwent endoscopic DCR (67 males and 106 females). The mean age was 51.8 years (range of 18 to 72). A stent was used in 92 patients (53.2 %) and not used in 81 patients (46.8 %). With silicone tubing the success rate was 96 %, and without silicone tubing it was 91 %, an overall success rate of 94 %. The odds ratio (OR) of failure without a silicone tube was 3.25 but CI was from 0.84 to 12.60 and the difference between these 2 groups was not statistically significant (p = 0.117). The author concluded that in this study, there was no statistically significant advantage of using endoscopic DCR with stent over the endoscopic DCR without stent.

In a randomized clinical trial, Chong and colleagues (2013) studied the effect of bi-canalicular silicone intubation on endonasal endoscopic mechanical dacryocystorhinostomy (EEM-
DCR) for primary acquired nasolacrimal duct obstruction (PANDO). A total of 120 consecutive adults (103 females) with a presenting age of 64 ± 13.7 years (range of 39 to 92) underwent EEM-DCR for PANDO from November 2005 to May 2009 in a lacrimal referral center. The EEM-DCR was performed by 2 lacrimal surgeons using standard techniques. Patients were randomly assigned to receive or not receive bi-canalicular silicone intubation for 8 weeks. No anti-metabolite was used. All patients received a course of oral antibiotics during non-absorbable nasal packing for flaps tamponade, which was removed at the first post-operative visit. Patients were assessed at 1, 3, 6, 12, 26, and 52 weeks after the operation. Surgical success was defined by symptomatic relief of epiphora, re-establishment of nasolacrimal drainage confirmed by irrigation by 1 masked observer, and positive functional endoscopic dye test by the operative surgeon at 12 months post-operatively. Intra-operative and post-operative complications were recorded. A total of 118 of the 120 randomized cases completed 12 months of follow-up. Two patients died of unrelated medical illnesses during follow-up. At 12 months post-operatively, there was no statistical difference in the success rate between patients with (96.3 %) and without (95.3 %) intubation (p = 0.79). The OR of failure without silicone intubation was 1.28 (95 % CI: 0.21 to 7.95). There was no difference in the incidence (p = 0.97) or the time to develop (p = 0.12) granulation tissue between the 2 groups. No significant difference was found between successful and failed cases in terms of age (p = 0.21), sex (p = 0.37), laterality (p = 0.46), mode of anesthesia (p = 0.14), surgeon (p = 0.26), use of stent (p = 0.79), or presence of granulation tissue postoperatively (p = 0.39). The authors concluded that the current study design provided 90 % statistical power to detect more than 21 % difference in surgical outcome, and no such difference was found whether intubation was used or not used in EEM-DCR for PANDO at the 12-month follow-up.

Ali and Naik (2014) reported the outcomes of endoscopic guided anterograde 3-mm balloon dacryoplasty with silicone intubation in patients with acquired partial nasolacrimal duct obstructions in adults. This retrospective case-series study included 21 eyes with partially obstructed nasolacrimal ducts of 12 patients. All the 21
ducts were initially probed and the probe confirmed with an endoscope in the inferior meatus. After confirming the presence of probe in the inferior meatus, a 3-mm balloon was used for dilating the distal and proximal portions of nasolacrimal duct, followed by stenting of ducts with Crawford tubes. Main outcome measures were anatomical patency of the passage and resolution of epiphora. Of the 12 patients, 9 had bilateral and 3 had unilateral acquired partial nasolacrimal duct obstructions. All the patients underwent bi-canalicular stenting under endoscopic guidance, which were retained for a period of 12 weeks. A minimum follow-up of 6 months following stent removal was considered for final analysis; 15 of the 21 ducts (71 %) were freely patent on irrigation, but 13 of the 21 (62 %) reported improvement of epiphora. Two nasolacrimal ducts showed similar partial regurgitation and partial patency on syringing as before with no improvement of symptoms. Four nasolacrimal ducts were completely obstructed with complete regurgitation of fluid on syringing with worsening of the epiphora. Two eyes persisted with symptoms of epiphora despite patent nasolacrimal duct with grade 2 dye retention on dye disappearance test. The authors concluded that 3-mm balloon dacryoplasty is an alternative and safe way to manage partial nasolacrimal duct obstructions with an anatomical success in 71 % and functional success in 62 % of the patients. Moreover, they stated that further studies with a large sample size and longer follow-up are needed to ascertain the long-term benefits.

Dotan et al (2015) studied predictors and implications on outcome of premature silicone tube-loss, a post-operative complication of mono-canalicular intubation (MCI) performed for treatment of congenital nasolacrimal duct obstruction (CNLDO). These researchers conducted a retrospective analysis of cases of post-operative loss of mono-canalicular silicone tubes occurring at one medical center from January 2007 to December 2013. During the study period, mono-canalicular silicone tubes were lost in 24/54 eyes (44 %) of 19/46 children. Multi-variate regression analysis identified bilateral intubation as an important predictor of early tube-loss (r = 0.54, p = 0.006); 7 of 8 (88 %) children who had both eyes intubated prematurely lost their tubes compared to 12/38 (32 %) children who had unilateral
intubation ($p = 0.005$). Treatment success was lower in eyes with early tube-loss (17/24 eyes, 71 %) compared to eyes with full tube retention (25/30 eyes, 83 %), however this difference was not statistically significant ($p = 0.333$). In this study, treatment outcome correlated with duration of intubation ($r = 0.51$, $p = 0.002$). Surgical success was achieved in 33/39 eyes (85 %) in which the tubes were retained at least 2 months compared to 7/15 eyes (47 %) with shorter period of intubation ($p = 0.012$).

The authors concluded that spontaneous tube-loss is a post-operative complication of mono-canalicular silicone intubation that can occur more frequently than previously reported in certain populations. Tube-loss occurring soon after surgery is often associated with persistent symptoms and increased need of re-operation.

Furthermore, an UpToDate review on “Nasolacrimal duct obstruction (dacryostenosis) in children” (Paysse et al, 2015) states that “Children who are older or have tight obstructions, anatomic abnormalities, or recurrence of obstruction after primary nasolacrimal duct probing may require the placement of a silicone stent or balloon dilation of the nasolacrimal duct (balloon dacryocystoplasty). Both of these procedures are performed with the child under general anesthesia. Stents usually are removed in the office after two to six months. Stents typically are not necessary with balloon dacryocystoplasty”.

**Dacryocystorhinostomy for Nasolacrimal Duct Obstruction (NDO):**

Dacryocystorhinostomy (DCR) involves creation of a new opening between the lacrimal sac and nasal cavity, usually at the level of the lacrimal sac itself (Lueder, et al., 2015). In children, this procedure is reserved for patients who have persistent symptoms despite undergoing nasolacrimal duct probing plus balloon catheter dilation or lacrimal stenting, DCR can be performed via a skin incision, with exposure of the lacrimal sac, creation of an osteotomy through the nasal bone, formation of flaps between the lacrimal sac and nasal mucosa, and placement of lacrimal stents (Lueder, et al., 2015). Laser probes are an alternative, with creation of an ostium utilizing a laser placed through the canaliculus and adjacent to the nasal bone (Kalyam, et al., 2014).
Endoscopy is usually used during laser DCR, and stents are placed at the end of the procedure.

Taskiran Comez and co-workers (2014) compared the success, complication, and patient discomfort rates of transcanalicular diode laser dacryocystorhinostomy (TCDL-DCR) and EXT-DCR surgeries performed in patients with PANDO. A total of 80 consecutive patients were included in the study, and groups were assigned according to DCR technique; 34 (42.5 %) patients received TCDL-DCR (Group A) and 46 (57.5 %) patients (Group B) received EX-DCR with temporary silicone stent intubation. The success of surgery was determined by the relief of epiphora, patient satisfaction, endoscopic evaluation of ostium patency, and lacrimal system syringing. Pearson Chi-Square test, Fisher’s Exact test, and Student’s t-test were used for statistical analyses. Group A included 22 females and 12 males with a mean age of 49.1 ± 15.1 years, Group B included 35 females and 11 males with a mean age of 50.8 ± 11.7 years. There was no difference between groups in terms of age and gender (p = 0.905, and p = 0.167, respectively). The duration of the operation was 22.2 ± 4.8 minutes for Group A, while it was 56.3 ± 15.7 minutes for group B (p = 0.0001). In 2 patients in Group A, injury in the medial turbinate was recorded, and in Group B, 14 patients experienced mild-to-severe peri-operative bleeding. The peri-operative complication rate was significantly different between the groups (p = 0.004). Success in relieving symptoms was 79.4 % for Group A and 89.1 % for Group B. The difference in the success rates was not statistically significant (p = 0.229). The authors concluded that although EXT-DCR success rate was higher than that achieved with TCDL-DCR, the latter, with its shorter duration of surgery, lower peri-operative complication rate, and a similar success rate, may be a good and acceptable surgical alternative in treatment of PANDO.

In a retrospective, non-comparative, non-randomized, interventional study, Kaynak and colleagues (2014) evaluated the success rate of 980-nm TCDL-DCR in patients with PANDO and considered the time and the reasons of failure. A total of 125 patients (130 eyes) who underwent of TCDL-DCR for the treatment of PANDO were included in this trial. The mean follow-
up time was 24.29 months (range of 8 to 34). Functional success was described as disappearance of epiphora and presence of a patent ostium on lacrimal irrigation. Anatomical success was described as a patent ostium to irrigation, but continuing epiphora. Patients with persistent epiphora and a closed ostium were classified as a surgical failure. At the 3rd month follow-up, 85.4% of cases had complete resolution of their symptoms. The functional success rate decreased to 67.7% at 6 months, to 63.3% at 1st year, and to 60.3% at 2nd year, while the patency of the lacrimal drainage system was restored in 93.1%, 74.6%, 69.5%, and 68.2% of the cases, respectively. The average total amount of delivered laser energy was 1,322.7 J. No correlation could be found between the age of the patient, delivered laser energy, and the surgical success (p = 0.38, p = 0.62). The authors concluded that TCDL-DCR was a fast and relatively easy alternative surgical method, which avoided a facial skin scar, to treat PANDO. The functional success rate was higher in the first months, but decreased to low 60%’s at the end of 1st year and remained the same at the 2nd-year follow-up.

Koch and associates (2016) stated that external DCR is currently the gold standard for the surgical treatment of ANDO, but tremendous progress has been made in recent years in improving minimally invasive techniques, sparing not only the skin, but also the medial lid structures, which contribute to the physiological palpebral-canalicular pump mechanism. These researchers reported their 1-year experience with the surgical technique, complications and results of transcanalicular laser assisted DCR (TKL-DCR). A total of 48 consecutive TKL-DCRs combined with bicanalicular silicone intubation were performed for ANDO, and evaluated for intra- and post-operative complications, as well as subjective and objective success rates; TKL-DCR combined with bicanalicular silicone intubation was surgically feasible in 45 cases (94%). In 3 patients (6%) it was impossible to position the aiming beam correctly at the antero-inferior rim of the middle turbinate using the superior canalicular approach, due to superior orbital rim prominence. Therefore, 2 patients received no silicone intubation, despite a patent osteotomy at the back of the middle turbinate, and 1 patient underwent intra-operative conversion to external DCR due to anatomical narrowness of the nasal cavity.
Peri-operatively, 1 patient developed canalicular infection, 1 patient exhibited thermal injury to the canaliculus, and 4 patients exhibited premature prolapse of the silicone tube. At 6-months follow-up, functional success (defined as resolution of pre-operative symptoms) was achieved in 35 of 45 (78 %) surgically successful TKL-DCRs. Of the 10 post-operative failures (22 %), all patients reported epiphora, 6 patients were unable to irrigate the lacrimal drainage system, and 6 patients required surgical revision using external DCR. The authors concluded that TKL-DCR is a promising minimally invasive approach for the surgical treatment of ANDO, in order to fill the gap between re-canalizing first-step procedures and external DCR.

Koch and colleagues (2017) noted that in recent years, the minimally invasive surgical procedure of TKL-DCR has gained importance in the treatment of PANDO. These investigators presented and compared surgical indications, functional success rates, potential advantages, and complications of TKL-DCR with EXT-DCR and EN-DCR. The study comprised a PubMed literature review and the authors’ own clinical results. Using TKL-DCR either as the primary surgical treatment for PANDO, or as a secondary procedure following failure (re-obstruction of the surgical ostium) of previous EXT-DCR resulted in good functional success rates (60 to 90 %). The duration of surgery (10 to 15 minutes) and the period of recovery were significantly shorter than in EXT-DCR. Visible cutaneous scars and significant post-operative nose bleeding were not among the complications of TKL-DCR, due to the lack of a skin incision and the coagulative ability of the diode laser. The smaller sized surgical ostium has been considered the main disadvantage of TKL-DCR, since it might be prone to earlier re-obstruction. On the other hand, TKL-DCR spared the anatomical structures that form the physiological tear pump, which should favor tear drainage. In very few cases, thermal damage to the canaliculus has been observed as a complication. The authors concluded that given the satisfying functional results, TKL-DCR is a valid alternative to the "gold standard" procedure EXT-DCR, especially in patients who particularly request speedy recovery and who do not want to take the risk of visible skin scaring. They stated that future studies will have to examine if the smaller surgical ostia of TKL-DCR remain
patent and whether functional success rates decrease during a longer follow-up period of greater than 2 years.

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<th>CPT Codes / HCPCS Codes / ICD-10 Codes</th>
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The above policy is based on the following references:


Silicone Stenting in Balloon Dacryocystoplasty:


4. Marcet MM, Kuk AK, Phelps PO. Evidence-based review of surgical practices in endoscopic endonasal dacryocystorhinostomy for primary acquired nasolacrimal duct obstruction and other new indications. Curr Opin...


**Dacryocystorhinostomy for Nasolacrimal Duct Obstruction:**


Amendment to
Aetna Clinical Policy Bulletin Number: 0420
Nasolacrimal Duct Obstruction: Treatments

There are no amendments for Medicaid.