2.01.71	Nonpharmacologic Treatment of Rosacea		
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Section:	2.0 Medicine	**Page:**	Page 1 of 22

Policy Statement

I. Nonpharmacologic treatment of rosacea is considered **investigational**, including but not limited to the following:
   A. Chemical peels
   B. Dermabrasion
   C. Electrosurgery
   D. Laser and light therapy
   E. Surgical debulking

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

Policy Guidelines

Coding
See the Codes table for details.

Description

Rosacea is a chronic, inflammatory skin condition without a known cure; the goal of treatment is symptom management. Nonpharmacologic treatments, including laser and light therapy as well as dermabrasion, which are the focus of this evidence review, are proposed for patients who do not want to use or are unresponsive to pharmacologic therapy.

Related Policies

- Chemical Peels
- Targeted Phototherapy and Psoralen with Ultraviolet A for Vitiligo

Benefit Application

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

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

Regulatory Status

Several laser and light therapy systems have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for various dermatologic indications, including rosacea. For example, rosacea is among the indications for:

- Vbeam laser system (Candela)

- Stellar M22™ laser system (Lumenis)
- excel VT®, excel V®, and xeo® laser systems (Cutera)
- Harmony® XL multi-application platform laser device (Alma Lasers, Israel)
- UV-300 Pulsed Light Therapy System (New Star Lasers)
- CoolTouch® PRIMA Pulsed Light Therapy System (New Star Lasers).

FDA product code: GEX.

Rationale

Background

Rosacea

Rosacea is characterized by episodic erythema, edema, papules, pustules, and telangiectasia that occur primarily on the face but also present on the scalp, ears, neck, chest, and back. On occasion, rosacea may affect the eyes. Patients with rosacea tend to flush or blush easily. Because rosacea causes facial swelling and redness, it is easily confused with other skin conditions such as acne, skin allergy, and sunburn.

Rosacea mostly affects adults with fair skin between the ages of 20 and 60 years and is more common in women, but often is most severe in men. Rosacea is not life-threatening, but if not treated, it may lead to persistent erythema, telangiectasias, and rhinophyma (hyperplasia and nodular swelling and congestion of the skin of the nose). The etiology and pathogenesis of rosacea are unknown but may result from both genetic and environmental factors. Some theories on the causes of rosacea include blood vessel disorders, chronic *Helicobacter pylori* infection, Demodex folliculorum (mites), and immune system disorders.

While the clinical manifestations of rosacea do not usually impact the physical health status of the patient, psychological consequences from the most visually apparent symptoms (i.e., erythema, papules, pustules, telangiectasias) may impact quality of life. Rhinophyma, an end-stage form of chronic acne, has been associated with obstruction of nasal passages and basal cell carcinoma in rare, severe cases. The probability of developing nasal obstruction or basal or squamous cell carcinoma with rosacea is not sufficient to warrant the preventive removal of rhinophymatous tissue.

Treatment

Rosacea treatment can be effective in relieving signs and symptoms. Treatment may include oral and topical antibiotics, isotretinoin, b-blockers, alpha$_2$-adrenergic agonists (e.g., oxymetazoline, clonidine), and anti-inflammatories. Patients are also instructed on various self-care measures such as avoiding skin irritants and dietary items thought to exacerbate acute flare-ups.

Nonpharmacologic therapy has also been tried in patients who cannot tolerate or do not want to use pharmacologic treatments. To reduce visible blood vessels, treat rhinophyma, reduce redness, and improve appearance, various techniques have been used such as laser and light therapy, dermabrasion, chemical peels, surgical debulking, and electrosurgery. Various lasers used include low-powered electrical devices and vascular light lasers to remove telangiectasias, carbon dioxide lasers to remove unwanted tissue from rhinophyma and reshape the nose, and intense pulsed lights that generate multiple wavelengths to treat a broader spectrum of tissue.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures

are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Nonpharmacologic Treatment of Rosacea

Clinical Context and Therapy Purpose

The purpose of nonpharmacologic treatments is to provide a treatment option in individuals who have rosacea and do not want to use or are unresponsive to pharmacologic therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with rosacea. Rosacea is characterized by episodic erythema, edema, papules and pustules, and telangiectasia that occur primarily on the face. Clinical presentation varies among individuals.

Interventions

The therapies being considered are nonpharmacologic treatments. Nonpharmacologic treatment options include laser and light therapy, dermabrasion, chemical peels, surgical debulking, and electrosurgery. Laser and light therapies are typically used for persistent erythema or telangiectasia. During laser and light therapy, light energy is absorbed by hemoglobin in cutaneous vessels, which leads to vessel heating and coagulation. Lasers vary from low-powered electrical devices and vascular light lasers (for telangiectasias removal) to carbon dioxide lasers and intense pulsed lights that generate multiple wavelengths to treat a broader spectrum of tissue.

Frequency and duration of laser and light therapy sessions vary, from once to twice per month, for several months. Because light-based techniques do not cure rosacea, periodic treatments may be necessary to maintain symptom relief.

Comparators

The comparators of interest are pharmacologic therapies, which include oral and topical antibiotics, isotretinoin, β-blockers, alpha$_2$-adrenergic agonists (e.g., oxymetazoline, clonidine), and anti-inflammatories. The selection of a pharmacological agent is dependent on the clinical features present for an individual (e.g., redness, edema, papules and pustules).

Outcomes

The general outcome of interest is symptom reduction, which may include a change in redness of skin color or change in erythema score or telangiectasia score. Other outcomes of interest include a reduction in pain, subject satisfaction, and improvement in the quality of life.

Outcome measures can be assessed on treatment completion. Because laser and light therapy are not curative, outcomes can be measured months after treatment to assess symptom recurrence.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

A meta-analysis by Chang and Chang (2022) compared the efficacy of pulsed dye laser to intense pulsed light.[1,] Only RCTs comparing these 2 modalities were included, and erythema was the only outcome analyzed in meta-analysis.

A meta-analysis by Husein-ElAhmed and Steinhoff (2021) compared the efficacy and tolerability of pulsed dye laser to other laser and light therapies.[2,] Both randomized and non-randomized studies were considered for inclusion; background erythema, telangiectasias, pain, and treatment success were analyzed. The studies did not compare interventions with pharmacologic treatments or placebo controls, only pulsed dye laser to other laser and light therapies.

A Cochrane systematic review by van Zuuren et al (2015) assessed various interventions for rosacea.[3,]; the same authors updated their systematic review in 2019 with a focus on rosacea phenotypes.[4,]. In 2019, the authors identified only 7 trials on light and/or laser therapy, and the trials did not compare these interventions with pharmacologic treatments or placebo controls, although 2 studies evaluated laser therapy in combination with pharmacologic therapy. Trial findings on light and/or laser therapy were considered low-quality and were not pooled. The remainder of the RCTs in the review evaluated pharmacologic treatments.

Wat et al (2014) identified 9 studies on the efficacy of intense pulsed light (IPL) for treating rosacea.[5,] Two studies were controlled (left-right comparisons), and the remainder were uncontrolled, including a case report.

The systematic reviews by van Zuuren et al (2019) and Wat et al (2014) did not pool study findings on the nonpharmacologic treatment of rosacea. Findings of the published systematic reviews highlight the shortage of RCTs on light and laser therapy for treating rosacea.

Table 1 compares the studies included in the systematic reviews. Tables 2 and 3 summarize the characteristics and results of the reviews, respectively.

Table 1. Comparison of Trials/Studies Included in Systematic Reviews of Nonpharmacologic Treatment of Rosacea

Study	Wat et al (2014)[5]	van Zuuren et al (2019)[4]	Husein-ElAhmed and Steinhoff (2021)[2]	Chang and Chang (2022)[1]
West et al (1998)[6]			●	
Mark et al (2003)[7]	●			
Taub et al (2003)[8]	●			
Schroeter et al (2005)[9]	●			
Karsai et al (2008)[10]		●		
Papageorgiou et al (2008)[11]	●			
Neuhaus et al (2009)[12]	●	●	●	
Lane et al (2010)[13]	●			
Nymann et al (2010)[14]		●	●	
Fabi et al (2011)[15]	●			
Kassier et al (2011)[16]	●			
Kim et al (2011)[a][17]		●		
Huang et al (2012)[a][18]		●		
Tanghetti et al (2012)[19]			●	
Alam et al (2013)[20]		●	●	
Salem et al (2013)[21]			●	
Friedmann et al (2014)[22]	●			
Seo et al (2016)[23]		●	●	
Handler et al (2017)[24]			●	●
Kim et al (2017)[25]			●	
Kwon et al (2018)[26]			●	
Campos et al (2019)[27]			●	
Kim et al (2019)[28]			●	●
Tirico et al (2020)[29]				●

[a] Study evaluated lasers in combination with other therapies. They are listed for completeness but are not included in the results table below.

Table 2. Systematic Review and Meta-Analysis Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Wat et al (2014)[5]	2003 to 2013	9	Patients with rosacea who received IPL	304 (1 to 102)	2 prospective right-left comparison, 3 OL trials, 3 retrospective, 1 case report	1 to 24 weeks
Van Zuuren et al (2019)[4]	2008 to 2016	7	Patients with rosacea who received laser and light therapies	233 (16 to 60)	RCT	4 to 24 weeks
Husein-ElAhmed and Steinhoff (2021)[2]	1998 to 2019	12	Patients with rosacea who received laser and light therapies	262 (9 to 39)	11 RCTs, 1 prospective right-left comparison	1 to 6 months
Chang and Chang (2022)[1]	2017 to 2020	3	Patients with rosacea who received pulsed dye laser and IPL	29 (5 to 15)	RCT	4 to 12 weeks

IPL: intense pulsed laser; OL: open-label; RCT: randomized controlled trial.

Table 3. Systematic Review & Meta-Analysis Results

Study (Year)	Reduced erythema	Reduced telangiectasia	Reduced blood flow	Visual clearance	Adverse events
Wat et al (2014)[5,]					
Total N	300	201	4	60	304
Pooled effect	Seen in 21% to 83% of patients	Seen in 29% to 55% of patients	30% decrease observed in 1 study	Seen in 75% to 87% of patients in 1 study	Included mild itch, edema, bruising, erythema purpura, pain, hyperpigmentation, and blister
p	p<.05 in 1 study, p<.001 in 1 study	p<.05 in 1 study, p<.001 in 1 study	p<.05 in 1 study	NR	NR
Van Zuuren et al (2019)[4,]					
Total N	65	56	NR	40	155
Pooled effect	Low to moderate certainty evidence for IPL, pulsed dye lasers, and Nd:YAG lasers; in 1 study, reduction in erythema index was similar with pulsed dye lasers vs dual wavelength lasers; in 1 study, erythema was reduced with pulsed dye lasers vs Nd:YAG lasers	Low to moderate certainty evidence for IPL, pulsed dye lasers, and Nd:YAG lasers; in 1 study, dual wavelength lasers led to greater improvement vs single wavelength lasers (RR, 4.5); 1 study reported no difference between IPL and pulsed dye laser	NR	Similar number of patients had 75% to 100% response and 50% to 74% response with IPL and long pulsed dye laser	Included purpura, erythema, crusts, hyperpigmentation, vesicles, dryness, itch, tightening, swelling, pain
p	p=.02 in 1 study of pulsed dye lasers vs Nd:YAG lasers	NR	NR	NR	NR
Husein-ElAhmed and Steinhoff (2021)[2,]					
Total N	69	NR	NR	148	185
Pooled effect	Pulsed dye lasers vs other laser and light therapies: mean difference, 0.90 (95% CI, -0.99 to 2.79)	Pulsed dye lasers vs other laser and light therapies: RR, 0.54 (95% CI, -0.87 to 1.94)	NR	Treatment success per physician assessment, pulsed dye lasers vs other laser and light therapies: OR, 1.23 (95% CI, 0.74 to 2.04)	Pain, pulsed dye lasers vs other laser and light therapies: mean difference, -0.23 (95% CI, -0.96 to 0.49)
p	p=.35	NR	NR	p=.43	p=.53
Chang and Chang (2022)[1,]					
Total N	29	NR	NR	NR	NR
Pooled effect	SMD:-0.112 (95% CI, -0.669 to 0.446)				
p	p=.695				

CI: confidence interval; IPL: intense pulsed light; Nd:YAG: neodymium-doped yttrium aluminum garnet; NR: not reported; OR, odds ratio; RR: relative risk; SMD: standard mean difference.

Randomized Controlled Trials

Several randomized trials evaluating nonpharmacologic treatment for rosacea, almost all of which used split-faced designs, were identified.[20,30,12,10,27,28,29,31,32,] Most compared 2 types of lasers, and only 1 used a placebo control or a pharmacologic treatment as a comparator. Additional RCTs were identified that evaluated the combination of nonpharmacologic and pharmacologic treatments against nonpharmacologic or pharmacologic treatment alone.[33,34,35,36,] No RCTs evaluating dermabrasion, chemical peels, surgical debulking, or electrosurgery for treating rosacea were identified.

Most studies reported a significant difference in erythema compared to baseline with laser treatments, but no studies found significant differences between laser modalities. For telangiectasia, significant improvements were observed with laser treatments, but only the study by Karsai et al (2008) reported a significant difference between laser modalities in favor of dual wavelength compared to single wavelength.[10,] In the RCT by Campos et al (2019), the primary outcome of change in Dermatology Life Quality Index was significant compared to baseline after the first (p<.001), second (p=.018), and third (p=.001) treatments.[27,] Three studies reported positive findings in subjective measures of patient satisfaction, including patient assessment of change in erythema.[20,30,12,] Adverse effects in these studies were mild and transient overall. One study reported a significant difference in pain, which was in favor of pulsed dye laser compared to neodymium-doped yttrium aluminum garnet (Nd:YAG) lasers.[20,] One RCT reported similar improvements in erythema with pulsed dye laser with topical oxymetazoline compared to topical oxymetazoline alone.[33,] A more recent RCT reported greater improvement in erythema with broadband light (intense pulsed light) plus intradermal botulinum toxin compared to broadband light alone.[35,]

A summary of key RCT characteristics and results is presented in Tables 4 and 5, respectively. Tables 6 and 7 provide an overview of the relevance and study design/conduct limitations of these RCTs.

Table 4. Summary of Key Randomized Controlled Trial Characteristics

					Description of Interventions	
Study	**Countries**	**Sites**	**Dates**	**Participants**	**Active**	**Comparator**
Karsai et al (2008)[a10,]	Germany	1	2006	Patients with nasal telangiectasia with similar vessel densities on both sides and vessel size <0.6 mm	Pulsed dye laser or Nd:YAG laser on 1 side of the face (n=20) Single treatment	Dual wavelength laser on opposite side of the face (n=20)
Neuhaus et al (2009)[a12,]	US	1	NR	Patients age 18 years or older with moderate erythematotelangiectatic rosacea with background erythema and small vessels (<1 mm) involving the central face	Pulsed dye laser on 1 side of the face (n=22) Pulsed dye laser (n=4) or IPL (n=4) on 1 side of the face 3 treatments separated by 4 weeks each	IPL on opposite side of the face (n=22) No treatment on opposite side of the face (n=8)
Maxwell et al (2010)[a30,]	Canada	1	NR	Patients with erythematotelangiectatic acne rosacea, a personal history of flushing, a family history of rosacea, and rosacea exacerbation by sun, alcohol, and/or spicy food	532 nm long-pulse laser on 1 side of the face (n=11) 6 treatments over 3 months, combined with topical retinaldehyde	Topical retinaldehyde treatment alone on opposite side of the face (n=11)

					Description of Interventions	
Alam et al (2013)[a20,]	US	1	NR	Patients age 18 years or older with erythematotelangiectatic rosacea	Pulsed dye laser on 1 side of the face (n=14) 4 treatments every 3 to 4 weeks	Nd:YAG laser on opposite side of the face (n=14)
Campos et al (2019)[a27,]	Spain	1	2015	Patients age 18 years or older with erythematotelangiectatic rosacea and no laser treatment within the past year	Pulsed dye laser on 1 side of the face (n=27) 4 treatments every 3 to 4 weeks	Multiplex pulsed dye laser/Nd:YAG laser on opposite side of the face (n=27)
Kim et al (2019)[a28,]	Korea	1	NR	Patients with rosacea	Short pulse IPL on 1 side of the face (n=9) 4 treatments every 3 weeks	Pulsed dye laser on opposite side of the face (n=9)
Tirico et al (2020)[a29,]	US	1	2016	Patients age 18 years or older with facial redness and none or mild tan	Short pulse IPL on 1 side of the face (n=5) 2 treatments separated by 4 to 6 weeks	Pulsed dye laser on opposite side of the face (n=5)
Sodha et al (2021)[33,]	US	1	NR	Patients age 18 years or older with erythematotelangiectatic rosacea	Pulsed dye laser (3 treatments every 4 weeks) plus daily topical oxymetazoline 1% (n=17)	Daily topical oxymetazoline 1% (n=13)
Osman et al (2022)[34,]	Egypt	1	NR	Patients with erythematotelangiectatic or papulopustular rosacea	Pulsed dye laser (4 treatments every 4 weeks) plus daily topical ivermectin 1% (n=15)	Pulsed dye laser alone (n=15)
Tong et al (2022)[a35,]	China	1	2021	Patients 14 years or older with rosacea with erythema and flushing as primary symptoms and inadequate response to traditional pharmacologic treatment; no local or systemic pharmacologic treatment within the past 2 weeks	IPL (3 treatments every 4 weeks) plus one-time intradermal botulinum toxin on 1 side of the face (n=22)	IPL plus one-time intradermal saline injection on opposite side of the face (n=22)
Barbarino et al (2022)[a36,]	US	1	NR	Patients 18 to 80 years with moderate-to-severe rosacea including erythema and telangiectasia; no local or systemic therapy within the past 2 weeks	IPL (one treatment) plus the following to right side of face only: phyto-corrective mask application (once per week), phyto-corrective gel (twice daily), topical	IPL (one treatment) alone on opposite side of face (n=10)

					Description of Interventions	
					resveratrol (once daily) (n=10)	
Park et al (2022)[a31,]	Korea	1	2021	Patients with erythematotelangiectatic or papulopustular rosacea not treated with antibiotics within the past 4 weeks or with laser treatment within the past 3 months	Long-pulsed alexandrite laser on 1 side of the face (n=23) (4 treatments every 4 weeks)	Pulsed dye laser on opposite side of the face (n=23)
Yang et al (2023)[32,]	China	1	2020-2021	Patients 18 to 65 years with moderate-to-severe rosacea; no phototoxic or photosensitizing drugs within 2 months	ALA-PDT for 3 to 5 sessions (n=20)	Minocycline 100 mg daily for 8 weeks (n=21)

ALA-PDT: 5-aminolevulinic acid photodynamic therapy; IPL: intense pulsed light; Nd:YAG: neodymium-doped yttrium aluminum garnet; NR: not reported.
[a]Split face design, yielding an equal number of patients in each treatment group.

Table 5. Summary of Key Randomized Controlled Trial Results/Outcomes

Study (Year)	Change in erythema	Change in telangiectasia	Adverse events
Karsai et al (2008)[10,]	**Dual wavelength vs. single wavelength**		
Percentage, p	NR	>50% vessel clearance: 90% vs. 20%, p<.0001	Transient purpura, posttreatment erythema
Neuhaus et al (2009)[12,]	**IPL vs. pulsed dye laser**		
Percentage, p	Malar and alar regions (both treatments): NS Cheek region: IPL vs. control, p=.04; Pulsed dye laser vs. control, p=.05 All locations: IPL vs. pulsed dye laser, NS	Malar and alar region: Pulsed dye laser vs control, both p=.02 IPL vs. control, p=.016 and p=.09, respectively IPL vs. pulsed dye laser, NS	NR
Maxwell et al (2010)[30,]	**Laser vs. no laser treatment**		
Percentage, p	Mild/moderate improvement: 100%	Mild/moderate improvement: 100%	NR
Alam et al (2013)[20,]	**Pulsed dye laser vs. Nd:YAG**		
Difference (95% CI), p	Pulsed dye laser vs. baseline: 8.9% (95% CI, -12.9% to -4.95%), p=.0003 Nd:YAG vs. baseline: 2.5% (95% CI, -6.37% to 1.29%), p=.1762 Pulsed dye laser vs. Nd:YAG: p=.199	NR	Pain: Worse with Nd:YAG vs. pulsed dye laser (p=.0028)
Campos et al (2019)[27,]	**Pulsed dye laser vs. multiplexed laser**		
Difference, p	Erythema index mean change: No difference between treatments (at 3 facial areas), p=.231, p=.674, p=.966, respectively	NR	Adverse effects: 48.1% to 55.6% (pulsed dye laser), purpura most common 14.8% to 33.3% (multiplexed laser), edema most common
Kim et al (2019)[28,]	**Short pulse IPL vs. pulsed dye laser**		
Difference, p	Erythema index mean change: -4.93±1.59 (short pulse IPL) -4.27±1.23 (pulsed dye laser) Difference between treatments: NS	NR	None observed

Study (Year)	Change in erythema	Change in telangiectasia	Adverse events
Tirico et al (2020)[29,]	**Short pulse IPL vs. pulsed dye laser**		
Difference, p	Improvement: 60% vs. 45%, NS	NR	Mild pain (mean scores 3.5 to 3.6 for short pulse IPL, mean scores 2.6 to 2.8 for pulsed dye laser)
Sodha et al (2021)[33,]	**Pulsed dye laser + oxymetazoline vs. oxymetazoline alone**		
Difference, p	Clinical Erythema Assessment, change from baseline: Combination: -0.6, -0.7, and -1.2 at 1-, 2-, and 3-months (p ≤.01 compared to baseline for all) Oxymetazoline alone: -0.6, -1.2, and -0.9 at 1-, 2-, and 3-months (p ≤.01 compared to baseline for all)	NR	Adverse effects: Pulsed dye laser: transient erythema (87%), edema (51%), and purpura (30%) Oxymetazoline (both groups): mild dryness (7%)
Osman et al (2022)[34,]	**Pulsed dye laser + ivermectin vs. pulsed dye laser alone**		
Difference, p	Erythema severity grade significantly reduced compared to baseline in both groups (p=.005 for combination, p=.001 for pulsed dye laser alone) Difference between treatments: p =.341	NR	Mild post-procedural purpura in both groups
Tong et al (2022)[35,]	**IPL + intradermal botulinum toxin vs. IPL alone**		
Difference, p	Erythema index mean change at 3 months: -93.03±42.33 (combination) -66.33±37.53 (IPL alone) Difference between treatments: p<.05	NR	Mild erythema and pain at injection site
Barbarino et al (2022)[36,]	**Phyto-corrective therapy + IPL vs. IPL alone**		
Difference, p	Not individually reported Efficacy represented by physician-assessed global aesthetic improvement scale at 3 months relative to baseline: Combination: 50%, 20%, and 30% improved, much improved, and very much improved, respectively IPL alone: 10%, 60%, and 20% improved, much improved, and very much improved, respectively	Not individually reported	NR
Park et al (2022)[31,]	**Long-pulsed alexandrite laser plus pulsed dye laser vs. pulsed dye laser alone**		
Difference, p	Erythema index mean change at 3 months after last treatment: -20.1%±15.4% (combination) -23.0%±18.7% (pulsed dye laser alone) Difference between treatments: p=.325	NR	Transient erythema or swelling
Yang et al (2023)[32,]	**Reduction in lesions (median, IQR)**	**Treatment success (n, %)**	**RosaQoL change (median, IQR)**

Study (Year)	Change in erythema	Change in telangiectasia	Adverse events
Difference, p	ALA-PDT: 19 (12 to 36) Minocycline: 22 (12 to 40) p=.75	ALA-PDT: 16 (80%) Minocycline: 17 (81%) p=1	ALA-PDT: 0.48 (0.19 to 1.22) Minocycline: 0.53 (-0.27 to 1.57) p=.64

ALA-PDT: 5-aminolevulinic acid photodynamic therapy; CI: confidence interval; IPL: intense pulsed laser; IQR: interquartile range; Nd:YAG: neodymium-doped yttrium aluminum garnet; NR: not reported; NS: not significant; RosaQoL.

Table 6. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Karsai et al (2008)[10,]			2 - no comparison to established pharmacologic treatment group alone	5 - clinically significant difference not prespecified	1 – only 1 treatment
Neuhaus et al (2009)[12,]			2 - no comparison to established pharmacologic treatment group alone	3 - no mention of harms 5 - clinically significant difference not prespecified	
Maxwell et al (2010)[30,]				3- no mention of harms 4 - major outcomes were patient-rated subjective improvements 5 - clinically significant difference not prespecified	
Alam et al (2013)[20,]			2 - no comparison to established pharmacologic treatment group alone	5 - clinically significant difference not prespecified	
Campos et al (2019)[27,]			2 - no comparison to established pharmacologic treatment group alone	5 - clinically significant difference not prespecified	
Kim et al (2019)[28,]			2 - no comparison to established pharmacologic treatment group alone	5 - clinically significant difference not prespecified	
Tirico et al (2020)[29,]				5 - clinically significant difference not prespecified	
Sodha et al (2021)[33,]			2 - missing inclusion of a laser-based treatment group only	5 - clinically significant difference not prespecified	
Osman et al (2022)[34,]			2 - no comparison to established	5 - clinically significant	

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
			pharmacologic treatment group alone	difference not prespecified	
Tong et al (2022)[35],			2 - no comparison to established pharmacologic treatment group alone	5 - clinically significant difference not prespecified	
Barbarino et al (2022)[36],	4 - only enrolled women	1 - details of intervention formulations and dosing unclear	2 - only a single laser therapy treatment administered; no comparison to established pharmacologic treatment group alone	1 - erythema, telangiectasia, and other disease outcomes not individually reported 3 - no reporting of harms 4 - invalid patient-reported outcomes 5 - clinically significant difference not specified 6 - clinically significant difference not supported	
Park et al (2022)[31],			2 - no comparison to established pharmacologic treatment group alone	3 - incomplete reporting of harms 5 - clinically significant difference not prespecified	
Yang et al (2023)[32],					

ALA-PDT: 5-aminolevulinic acid photodynamic therapy
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context for treatment is unclear; 3. Study population unclear; 4. Study population not representative of intended use; 5. Study population is subpopulation of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not established and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.
[e] Follow-up key: 1. Not sufficient duration for benefits; 2. Not sufficient duration for harms.

Table 7. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Karsai et al (2008)[10],		1 – no mention of patient blinding			1 – no mention of power	3 – p-value for primary efficacy comparison not reported

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Neuhaus et al (2009)[12],		1 – no mention of patient blinding			1 – no mention of power	
Maxwell et al (2010)[30],		1 – no mention of patient blinding 2 - most outcomes were patient-rated improvements, and patients were not blinded		6 - only reported results for patients that completed the study	1 – no mention of power	4 - treatments were not statistically compared
Alam et al (2013)[20],				6 - only reported results for patients that completed the study		
Campos et al (2019)[27],				6 - only reported results for patients that completed the study	1 – no mention of power	
Kim et al (2019)[28],		1 – no mention of blinding 2 – no mention of blinding				
Tirico et al (2020)[29],				6 - only reported results for patients that completed the study	1 - no mention of power	3 – p-value for efficacy comparisons not reported
Sodha et al (2021)[33],		1 – no mention of patient blinding 2 - some outcomes were patient-rated improvements, and patients were not blinded			2 - power not reported for primary outcome; authors noted adequate power not achieved due to closure of the clinic due to COVID-19	4 - change in erythema not compared between treatment arms
Osman et al (2022)[34],		1 - no mention of patient blinding	1 - not registered		1 - no mention of power	1 - test used to compare between arms unclear 2 - unclear if

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
						appropriate test used for multiple observations
Tong et al (2022)[35],		1 - no mention of patient blinding			1 - no mention of power	
Barbarino et al (2022)[36],		1 - no mention of blinding 3 - outcome assessed by treating physician	1 - not registered 2 - evaluation of reduction in procedure-related adverse events with intervention stated in study aims, but no safety results reported 3 - senior author is journal's editor-in-chief, third author is on journal's advisory committee		1 - no inferential statistical analysis	3 - no inferential statistical analysis 4 - no inferential statistical analysis
Park et al (2022)[31],				2 - details of handling data for dropout cases not reported 6 - dropout cases appear to be excluded from analysis, procedure not detailed	1 - no mention of power	
Yang et al (2023)[32],		1 - patients not blind				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

[c] Selective reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Follow-up key: 1. High loss to follow up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Test is not appropriate for outcome type: a) continuous; b) binary; c) time to event; 2. Test is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p-values not reported; 4. Comparative treatment effects not calculated.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Acne and Rosacea Society

In 2014, the American Acne and Rosacea Society issued consensus recommendations on the management of rosacea.[37,] The Society stated that lasers and intense pulsed light (IPL) devices could improve certain clinical manifestations of rosacea that have not responded to medical therapy. The recommendations indicated that these therapies would have to be repeated intermittently to sustain improvement.

In 2016, the American Acne and Rosacea Society issued updated consensus recommendations on the management of rosacea.[38,] The update focused on how medical and device therapies are used--whether concurrently or in a staggered fashion--noting that there is a lack of evidence to justify either use. The Society's consensus recommendation on rosacea management correlated with clinical manifestations observed at the time of presentation is summarized in Table 8:

Table 8. Recommendations on Use of Lasers and Intense Pulsed Light Devices for the Management of Rosacea

Condition	Recommendation	Grade[a]
Persistent central facial erythema without papulopustular lesions	IPL, potassium titanyl phosphate crystal laser, or pulsed dye laser	B
Diffuse central facial erythema with papulopustular lesions	"While the data on the use of IPL, potassium titanyl phosphate or pulsed dye laser are limited for papulopustular lesions, these options are useful to treat erythema"	NR
Granulomatous rosacea	• Intense pulsed dye laser • "No current standard of treatment; limited data based on case reports"	C
Phymatous Rosacea	• "Surgical therapy for fully developed phymatous changed (carbon dioxide laser, erbium-doped [YAG] laser, electrosurgery, dermabrasion)" • "Treatment selection dependent on stage of development (early or fibrotic) and extent of inflammation (active or burnt out)"	C

IPL: intense pulsed light, YAG: yttrium aluminum garnet; NR: not reported.
[a] Grade A: Criteria not described in recommendation; Grade B: Systematic review/meta-analysis of lower-quality clinical trials or studies with limitations and inconsistent findings; lower-quality clinical trial; Grade C:Consensus guidelines; usual practice, expert opinion, case series—limited trial data

National Rosacea Society

In 2019, the National Rosacea Society Executive Committee published an expert consensus document on management options for rosacea.[39,] This document endorses treatment goals of an Investigator Global Assessment score of 0 and normalization of skin tone and color due to the notable impact of rosacea on patient quality of life. Light devices are discussed as treatment options along with medications, skin care, and lifestyle interventions. Based on weak evidence, IPL, pulsed dye lasers, and potassium titanyl phosphate lasers are listed as moderately effective treatment options for persistent erythema, particularly due to telangiectasia. Both IPL and potassium titanyl phosphate

are described as having at least some efficacy for flushing. Nonpharmacologic interventions that are listed as more highly effective treatment options for non-inflamed phymas (based on weak evidence) include carbon dioxide lasers, erbium lasers, cold steel, electrosurgery, and radiofrequency; these same interventions are listed for use in combination with other treatment modalities for inflammatory phymas. Carbon dioxide lasers, erbium lasers, cold steel, electrosurgery, and radiofrequency carry a risk of post-inflammatory hyperpigmentation and should only be provided by appropriately trained individuals.

Rosacea Consensus Panel

In 2017, the Rosacea Consensus panel, comprised of international experts including representatives from the U.S., published recommendations for rosacea treatment.[40,] The panel agreed that treatments should be based on phenotype. IPL and pulsed dye laser were recommended for persistent erythema, but not for transient erythema. IPL and lasers were also recommended for telangiectasia rosacea.

The panel updated their recommendations on rosacea treatment in 2019, agreeing that lasers were recommended for persistent centrofacial erythema.[41,] They also noted that "use of IPL and vascular lasers in darker skin phototypes requires consideration by a healthcare provider with experience..., as it can result in dyspigmentation." The panel also acknowledged that combining treatments could benefit patients with more severe rosacea and multiple rosacea features; however "there remains an ongoing need for more studies to support combination treatment use in rosacea."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

No ongoing or unpublished trials were identified in a search of clinicaltrials.gov in October 2024.

NCT: national clinical trial.

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Documentation for Clinical Review

- No records required

Coding

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

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

Type	Code	Description
CPT®	15780	Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis)
	15781	Dermabrasion; segmental, face
	15782	Dermabrasion; regional, other than face
	15783	Dermabrasion; superficial, any site (e.g., tattoo removal)
	15788	Chemical peel, facial; epidermal
	15789	Chemical peel, facial; dermal
	15792	Chemical peel, nonfacial; epidermal
	15793	Chemical peel, nonfacial; dermal
	17106	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); less than 10 sq cm
	17107	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); 10.0 to 50.0 sq cm
	17108	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); over 50.0 sq cm
	17110	Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; up to 14 lesions
	17111	Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; 15 or more lesions
	30117	Excision or destruction (e.g., laser), intranasal lesion; internal approach
	30118	Excision or destruction (e.g., laser), intranasal lesion; external approach (lateral rhinotomy)
	30120	Excision or surgical planing of skin of nose for rhinophyma
HCPCS	E0691	Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; treatment area 2 sq ft or less
	E0692	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 4 ft panel
	E0693	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 6 ft panel
	E0694	Ultraviolet multidirectional light therapy system in 6 ft cabinet, includes bulbs/lamps, timer, and eye protection

Policy History

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

Effective Date	Action
10/15/2007	New Policy Adoption
10/28/2009	Coding Update
04/02/2010	Coding Update
07/01/2011	Policy revision without position change
06/30/2015	Coding update
10/30/2015	Policy title change from Non-Pharmacologic Treatment of Rosacea Policy revision without position change
03/01/2016	Policy revision without position change
06/01/2016	Coding update
02/01/2017	Policy revision without position change
02/01/2018	Policy revision without position change
02/01/2019	Policy revision without position change
02/01/2020	Annual review. No change to policy statement. Literature review updated.
02/01/2021	Annual review. No change to policy statement. Literature review updated.
02/01/2022	Annual review. No change to policy statement. Literature review updated.
02/01/2023	Annual review. No change to policy statement. Literature review updated.
02/01/2024	Annual review. No change to policy statement. Literature review updated.
02/01/2025	Annual review. No change to policy statement. Policy guidelines and literature review updated.

Definitions of Decision Determinations

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

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

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

Prior Authorization Requirements and Feedback (as applicable to your plan)

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

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

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

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

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

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Nonpharmacologic Treatment of Rosacea 2.01.71 **Policy Statement:** I. Nonpharmacologic treatment of rosacea is considered **investigational**, including but not limited to the following: A. Chemical peels B. Dermabrasion C. Electrosurgery D. Laser and light therapy E. Surgical debulking	**Nonpharmacologic Treatment of Rosacea 2.01.71** **Policy Statement:** I. Nonpharmacologic treatment of rosacea is considered **investigational**, including but not limited to the following: A. Chemical peels B. Dermabrasion C. Electrosurgery D. Laser and light therapy E. Surgical debulking