

Medical Coverage Policy

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit MUST be verified in the member's EOC or benefit document if it includes the optional rider.
- Please refer to CMS guidelines: National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Medicare members. This MCP applies if no CMS criteria are available.
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage purposes

I. Specialty: Dermatology

II. Coverage and Exclusions

We cover treatment of vitiligo to prevent sun damage to the skin and to decrease susceptibility of affected areas to skin cancer.

A. Covered Condition:

1. Vitiligo

B. Criteria and Limitations

- Treatment of vitiligo with photochemotherapy which includes psoralens (P) and type A ultraviolet (UVA) radiation, (combined as "PUVA") or narrow beam ultraviolet light (NB-UVB) should be restricted to patients who have not responded to topical and/or systemic corticosteroid therapy, tacrolimus or pimecrolimus.
- 2. Excimer Laser (XTRAC, PhotoMedex, Radnor, PA; EX-308, Ra Medical Systems, Inc Carlsbad, CA) therapy is NOT for treatment of extensive vitiligo. It is reserved only for localized disease that has been documented to be unresponsive to prior medical or phototherapy.
- 3. Home phototherapy treatment. It is most effective for UV sensitive areas (face, neck, back, breast and arm) with much less response to UV resistant areas (knees, elbows, wrists, hands, ankles, and feet. Phototherapy with the excimer laser (or other source of focal NB) has the advantage of applying targeted treatment only to the de-pigmented sites. NB-UVB, which has been studied more extensively, may also be useful (with larger units) for the treatment of extensive vitiligo, and is more advantageous when compared with the excimer laser in terms of costs, duration of treatment sessions and patient compliance.
- 4. Home based phototherapy (NB-UVB) is covered under Home Phototherapy MCP guidelines.



Medical Coverage Policy

Home phototherapy units would be subject to the DME coverage restrictions and subject to co-pay for the device.

C. Exclusions

- 1. Melanocyte transplantation for the treatment of vitiligo
- 2. Treatments for vitiligo that do not affect the underlying condition and do not result in improved protection against skin cancer; specifically, micropigmentation (tattooing) and depigmentation (with monobenzyl ether of hydroquinone/monobenzone) are considered cosmetic and are excluded from coverage.
- **3.** Tumor necrosis factors, prostaglandins, chimeric monoclonal antibodies and split thickness skin grafting are considered experimental and investigational and their effectiveness for treatment has not been established.
- 4. Helium Neon Laser, a gas laser which operates in the red spectrum at 632.8 nm, is a recent intervention for treating vitiligo. It is used as monotherapy but also in combination with tacrolimus, which looks promising, particularly as it is reported to be effective for segmental vitiligo which can be difficult to treat by conventional methods. There are yet no published RCTs of this intervention. At this time, this treatment is considered experimental and is excluded from coverage.

III. Definitions and Acronyms

Phototherapy - includes actinotherapy, type A ultraviolet (UVA) radiation; type B ultraviolet (UVB) radiation; and combination UVA/UVB radiation.

Photochemotherapy includes psoralens (P) and type A ultraviolet (UVA) radiation, known as PUVA photochemotherapy and combinations of P/UVA/UVB.

Excimer Laser - the excimer laser has a wavelength of 308nm.



Medical Coverage Policy

References

- 1. Agretti P. Patients affected by vitiligo and autoimmune diseases do not show antibodies interfering with the activity of the melanocortin 1 receptor. J Endocrinol Invest Dec 2010; 33(11): 784-8
- 2. Colucci R. Vitiligo: an update on current pharmacotherapy and future directions. Expert Opin Pharmacother Sep 2012; *13(13): 1885-99*
- 3. Eleftheriadou V. Future research into the treatment of vitiligo: where should our priorities lie? Results of the vitiligo priority setting partnership. Br J Dermatol Mar 2011; 164(3): 530-
- 4. Halder, Rebat, New Surgical techniques hold promise for treating vitiligo, American Academy of Dermatology, 70th Annual Meeting, March 2012.
- 5. Hossani-Madani A. Treatment of vitiligo: advantages and disadvantages, indications for use and outcomes. G Ital Dermatol Venereol Oct 2011; 146(5): 373-95
- 6. Lin, Xiao, Tang, Lu-Yan, et al. Childhood vitiligo in China: clinical profiles and immunological findings in 620 cases. Am J Clin Dermatol Aug 2011; 12(4): 277
- Menter A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 5. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. Journal of the American Academy of Dermatology 2010;62(1):114-35.
- 8. Medicare Coverage Database, Manual section number 250.1: Treatment of Psoriasis. Accessed 4/7/2015.
- 9. Millington GW, Levell NJ. Vitiligo. The historical curse of depigmentation. Int J Dermatol Sept 2007, 46(9):990-5.
- 10. Mouzakis, John, Liu, Stephanie et al. Rapid Response of Facial Vitiligo to 308nm Excimer Laser and Topical Calcipotriene. Clinical and Aesthetic Dermatology, Jun 2011; 4(6): 41-44.
- Nicolaidou, Electra, Antoniou, Christina, et al. Narrowband ultraviolet B phototherapy and 308-nm excimer laser in the treatment of vitiligo: A review. Journal of the American Academy of Dermatology – March 2009, Volume 60, Issue 3, 470-477.
- Ponte P, Serrao V, Apetato M. Efficacy of narrowband UVB vs. PUVA in patients with early-stage mycosis fungoides. Journal of the European Academy of Dermatology and Venereology: JEADV. 2009;24(6):716-21.
- 13. Soliman M, Samy NA, Abo Eittah M, Hegazy M. Comparative Study between Excimer Light and Topical Antioxidant versus Excimer Light alone for treatment of Vitiligo. J Cosmet Laser Ther. Jun 2015; 8:1-18.
- 14. Stern RS. Psoralen and ultraviolet A light therapy for psoriasis. New England Journal of Medicine 2007;357(7):682-90.
- 15. U.S. Nat'l Institutes of Health, Clinical Trial: NCT00615355, Epidermal Cell Transplantation in Vitiligo Skin With and Without Narrow-band Ultraviolet B (UVB) Treatment, February 13, 2013.
- 16. Van Driessche F, Silverberg N. Current Management of Pediatric Vitiligo. <u>Paediatr Drugs.</u> May 2015.
- 17. Wind, B, Meesters, A. et al Punchgraft testing in vitiligo: effects of UVA, NB-UVB and 632.8nm Helium-



Medical Coverage Policy

Neon laser on the outcome. J European Acad Derm and Venereology, Oct 2011, 25:10, 1236-1237.

- 18. Whitton, ME, Pinart, M. et al. Interventions for Vitiligo (Review): The Cochrane Collaboration. 2011, Issue 12.
- 19. Zhang XY Clinical efficacy of a 308nm excimer laser in the treatment of vitiligo; Photodermatol Photoimmunol Photomed June 2010; 26(3): 138-42.
- 20. The efficacy of narrowband UVB treatment in pediatric vitiligo: a retrospective analysis of 26 cases. Yazici, Serkan; Gunay, Berrin; Bulbul Baskan, Emel; Aydogan, Kenan; Saricaoglu, Hayriye; Tunali, Sukran. Turkish Journal of Medical Sciences. 2017, Vol 47 Issue 2, p381-384, 4p. Publisher: Scientific & Technical Research Council of Turkey, Database; Complimentary Index.
- 21. Cabrera, Raul; Hojman, Lia; Recule, Francisca; Sepulveda, Rodrigo; Delgado, Iris. Predictive Model for Response Rate to Narrowband Ultraviolet B Phototherapy in Vitiligo: A Retrospective Cohort Study of 579 Patients. Acta Dermato-Venereologica, Apr2018, Vol. 98 Issue 4, p416-420, 5p. Publisher: Society for Publication of Acta Dermato-Venereologica., Database: Complementary Index.
- 22. Ullah, Ghafoor; Rehman, Sumayya; Noor, Sahibzada Mehmood; Paracha, Muhammad Majid. Efficacy of tacrolimus plus narrowband ultraviolet B phototherapy versus narrowband ultraviolet B phototherapy alone in the treatment of vitiligo. *Journal of Pakistan Association of Dermatologists.* Jul-Sep2017, Vol. 27 Issue 3, p232-237. 6p. Database: Academic Search Index
- 23. Ji Hae Lee, Hyuck Sun Kwon, Han Mi Jung et al. Treatment Outcomes of Topical Calcineurin Inhibitor Therapy for Patients With Vitiligo. A Systematic Review and Meta-analysis *JAMA Dermatol.* 2019;155(8):929-938. doi:10.1001/jamadermatol.2019.0696
- 24. Zubair, Raheel; Hamzavi, Iltefat H. Phototherapy for Vitiligo *Dermatologic Clinics*. Language: English. DOI: 10.1016/j.det.2019.08.005, Database: ScienceDirect
- Sun, M. C., Xu, X. L., Lou, X. F., & Du, Y. Z. (2020). Recent Progress and Future Directions: The Nano-Drug Delivery System for the Treatment of Vitiligo. *International journal of nanomedicine*, 15, 3267–3279. https://doi.org/10.2147/IJN.S245326
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7217315/pdf/ijn-15-3267.pdf
 26. Komnitski, M., Komnitski, A., Komnitski Junior, A., & Silva de Castro, C. C. (2020). Partial repigmentation of vitiligo with tofacitinib, without exposure to ultraviolet radiation. *Anais brasileiros de dermatologia*, 95(4), 473–476. https://doi.org/10.1016/j.abd.2019.08.032
- https://pubmed.ncbi.nlm.nih.gov/32418716/
 27. Migayron, L., Boniface, K. & Seneschal, J. Vitiligo, From Physiopathology to Emerging Treatments: A Review. *Dermatol Ther (Heidelb)* 10, 1185–1198 (2020). https://doi.org/10.1007/s13555-020-00447-y. Accessed 07/27/2021
- Wang, Y., Li, S., & Li, C. (2019). Perspectives of New Advances in the Pathogenesis of Vitiligo: From Oxidative Stress to Autoimmunity. *Medical Science Monitor: International Medical Journal of Experimental and clinical research*, 25, 1017–1023. Accessed 07/27/2021 <u>https://doi.org/10.12659/MSM.914898</u>.



Medical Coverage Policy

- Kubelis-López, D. E., Zapata-Salazar, N. A., Said-Fernández, S. L., Sánchez-Domínguez, C. N., Salinas-Santander, M. A., Martínez-Rodríguez, H. G., Vázquez-Martínez, O. T., Wollina, U., Lotti, T., & Ocampo-Candiani, J. (2021). Updates and new medical treatments for vitiligo (Review). *Experimental and therapeutic medicine*, 22(2), 797. Accessed 07/27/2021. <u>https://doi.org/10.3892/etm.2021.10229</u>.
- Ragab, M., El Zagh, O., & Farid, C. (2021). Transverse Needling After Autologous Mini-Punch Grafts Improves Repigmentation in Stable Non-Segmental Vitiligo. *Clinical, cosmetic and investigational dermatology*, 14, 827–835. <u>https://doi.org/10.2147/CCID.S315407</u>
- Bertolotti, A., Leone, G., Taïeb, A., Soriano, E., Pascal, M., Maillard, H., & van Geel, N. (2021). Assessment of Non-cultured Autologous Epidermal Cell Grafting Resuspended in Hyaluronic Acid for Repigmenting Vitiligo and Piebaldism Lesions: A Randomized Clinical Trial. *Acta dermatovenereologica*, 101(7), adv00506. <u>https://doi.org/10.2340/00015555-3870</u>
- 32. Smith, M. P., Ly, K., Thibodeaux, Q., Bhutani, T., & Nakamura, M. (2019). Home phototherapy for patients with vitiligo: challenges and solutions. *Clinical, cosmetic, and investigational dermatology*, *12*, 451–459. <u>https://doi.org/10.2147/CCID.S185798</u>
- Ashraf, A. Z., Azurdia, R. M., & Cohen, S. N. (2022). The effectiveness of home-based phototherapy for vitiligo: A systematic review of randomised controlled trials. *Photodermatology, photoimmunology & photomedicine*, 38(5), 409–417. <u>https://doi.org/10.1111/phpp.12766</u>
- Dillon, A. B., Sideris, A., Hadi, A., & Elbuluk, N. (2017). Advances in Vitiligo: An Update on Medical and Surgical Treatments. *The Journal of clinical and aesthetic dermatology*, *10*(1), 15–28. https://pubmed.ncbi.nlm.nih.gov/28210378/
- 35. MCG Ambulatory Care 28th Edition, © 2024 MCG Health, LLC. ACG: A-0255 (AC) Phototherapy, Skin.
- 36. AL-smadi, K.; Imran, M.; Leite-Silva, V.R.; Mohammed, Y. Vitiligo: A Review of Aetiology, Pathogenesis, Treatment, and Psychosocial Impact. *Cosmetics* 2023, *10*, 84. <u>https://doi.org/10.3390/cosmetics10030084</u>
- Feng, Y. and Ly, Yan. Advances in vitiligo: Update on therapeutic targets. *Frontiers in Immunology*, 30 August 2022. Sec Vaccines and Molecular Therapeutics. Volume 13 – 2022. <u>https://doi.org/10.3389/fimmu.2022.986918</u>
- 38. Iltefat H Hamzavi, Kristen Bibeau, Pearl Grimes, John E Harris, Nanja van Geel, Davinder Parsad, Mukta Tulpule, Jackie Gardner, Yan Valle, Gaone Tlhong Matewa, Christine LaFiura, Haobo Ren, Khaled Ezzedine, Exploring the natural and treatment history of vitiligo: perceptions of patients and healthcare professionals from the global VALIANT study, *British Journal of Dermatology*, Volume 189, Issue 5, November 2023, Pages 569–577, <u>https://doi.org/10.1093/bjd/ljad245</u>
- Diotallevi, F.; Gioacchini, H.; De Simoni, E.; Marani, A.; Candelora, M.; Paolinelli, M.; Molinelli, E.; Offidani, A.; Simonetti, O. Vitiligo, from Pathogenesis to Therapeutic Advances: State of the Art. *Int. J. Mol. Sci.* 2023, *24*, 4910. <u>https://doi.org/10.3390/ijms24054910</u>



Medical Coverage Policy

Approval History

The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Date approved by	Date filed with the State of	Effective Date
RUMC	Maryland	(Ten days after filing)
06/30/2011	06/30/2011	07/11/2011
06/21/2012	06/21/2012	07/02/2012
06/28/2013	06/28/2013	07/09/2013
07/02/2014	07/07/2014	07/18/2014
07/30/2015	07/31/2015	08/11/2015

Approval History

Effective June 01, 2016, state filing no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
07/26/16	07/26/16
12/22/2016	12/22/2016
12/28/2017	12/28/2017
12/27/2018	12/27/2018
12/19/2019	12/19/2019
12/16/2020	12/16/2020
12/15/2021	12/15/2021
11/28/2022	11/28/2022
10/25/2023	10/25/2023
10/28/2024	10/28/2024

*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Whenever possible, Medical Coverage Policies are evidence-based. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.

©2024, Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. ©2024, Mid-Atlantic Permanente Medical Group, P.C