KAISER PERMANENTE® Mid-Atlantic States	**Microwave Thermolysis with miraDry System for Axillary Hyperhidrosis** **Medical Coverage Policy**

Utilization *ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- For Medicare members, please refer to CMS guidelines through Medicare Coverage Database requirements.
- This MCP applies if no CMS criteria are available.

I. Specialties: Dermatology, Surgery

II. Service/Device

A. **Microwave Thermolysis with miraDry System**

1. The microwave ablation of axillary sweat glands with the use of miraDry System is a third line treatment of primary axillary hyperhidrosis after creams and botox treatment have been tried and documented to have failed. It is designed to achieve reduction of excessive sweating in the underarm close to permanent sweat reduction possible.
2. Microwave thermolysis of both axillae is performed non-invasively under local anesthesia, in two 40-minute to 60-minute therapeutic sessions, spaced twelve weeks apart.
3. Adverse events that can occur following the procedure are expected to resolve from several days to a few weeks following miraDry ablation. Applying ice compress and taking non-steroidal anti-inflammatory drugs (NSAIDs) for the first few days following the procedure will help alleviate these adverse events:
   a. Localized mild to moderate edema;
   b. Bruising;
   c. Localized pain or soreness;
   d. Temporary change in skin sensitivity or sensation such as numbness in the axillae; and/or
   e. Hair loss in the armpit

B. miraDry System

1. The miraDry System by Miramar Labs, Inc. was approved by Food and Drug Administration (FDA) in January 2011 as a microwave soft tissue ablation system (product code NEY) to permanently destroy the axillary sweat glands.[1]

2. The therapeutic equipment uses precise beams of microwave thermal energy directed in the underarm area which result in thermolysis, permanent obliteration of axillary sweat glands and immediate cessation of excessive sweating in the underarm area.

3. miraDry System consists of a console system (microwave generator, vacuum and circulating hydroceramic cooling system) extended via cable to a handheld laser-like applicator called the

Handpiece

III. Indication, Contraindication and Limitations

A. Indications

1. miraDry System is a non-invasive third line treatment option for primary axillary hyperhidrosis who are not responsive to oral medications, topical creams and botox treatment, *and*
2. miraDry ablation requires clinical review and authorization by a Utilization Management Physician.

B. Contraindications

Mira Dry system is not indicated for the following conditions:

1. Presence of implanted electronic devices;
2. Known resistance to or intolerance of local anesthesia;
3. Hyperhidrosis related to other body areas or generalized hyperhidrosis

C. Limitations

- miraDry is not approved by FDA for generalized hyperhidrosis or focal hyperhidrosis outside the axillae.
- All other indications for miraDry System use other than primary axillary hyperhidrosis are considered ***experimental and investigational*** and are not covered.

References

1. ClinicalTrials.gov. Search results for "MiraDry Tx." Available at https://clinicaltrials.gov/ct2/show/NCT02295891?term=miradry&rank=1. Accessed 02.07.2017
2. American Society of Dermatologic Surgery. Microwave Thermolysis for Excessive Sweating Available at: https://www.asds.net/Microwave-Thermolysis-for-Excessive-Sweating/. Accessed on February 7, 2017.
3. International Hyperhidrosis Society. miraDry. Available at http://www.sweathelp.org/treatments-hcp/miradry.html. Accessed on February 7, 2017.
4. The Center for Sweat Disorders, John Hopkins University. Microwave Thermolysis for Excessive Sweating. http://www.hopkinsmedicine.org/sweat_disorders/hyperhidrosis/treatments/microwave_treatment.html. Accessed on February 7, 2017.
5. Kaiser Permanente Medical Technology Management Process, Southern California. Review date: June 2013. Available at: http://cl.kp.org/pkc/national/cpg/intc/scpmg/assessment/MTAT_miraDRY_June2013_FINAL.pdf
6. FDA's 510(k) Pre-market Notification Database. miraDry System 510(k) Number K103104. Approved January 28, 2011. Available at https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103014.pdf.

Accessed on February 6, 2017.
7. Cigna Healthcare. Medical Coverage Policy: Hyperhidrosis Treatment. Policy Number 0037. Effective date: 01/01/2017. Available at https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0037_coveragepositioncriteria_endoscopic_sympathectomy_for_hyperhidrosis.pdf
8. Aetna Medical Coverage Policy: Hyperhidrosis. Policy Number 0504. Effective date: 07/29/2016. Available at http://www.aetna.com/cpb/medical/data/500_599/0504.html.
9. Local Procedural Approaches for Axillary Hyperhidrosis by Glaser, Dee Anna; Galperin, Timur A. in Hyperhidrosis, Dermatologic Clinics. October 2014. 32(4): 533-540 Language: English DOI 10.1016/j.det.2014.06.14.
10. Nawrocki, Shiri; Cha, Jisun. The Etiology, Diagnosis and Management of Hyperhidrosis: A Comprehensive Review. Part II. Therapeutic Options *Journal of the American Academy of Dermatology*. January 2018 Language: English. DOI: 10.1016/j.jaad.2018.11.066, Database: ScienceDirect
11. Wechter T, Feldman SR, Taylor SL. The Treatment of Primary Focal Hyperhidrosis. *Skin Therapy Lett.* 2019 Jan;24(1):1-7. PMID: 30817880 http://www.skintherapyletter.com/hyperhidrosis/primary-focal-hyperhidrosis-treatment/
12. Nawrocki S, Cha J. The etiology, diagnosis, and management of hyperhidrosis: A comprehensive review: Therapeutic options. *J Am Acad Dermatol*. 2019 Sep;81(3):669-680. doi: 10.1016 /j.jaad.2018.11.066. Epub 2019 Jan 31. Review. PMID: 30710603 https://www.clinicalkey.com/service/content/pdf/watermarked/1-s2.0-S0190962219301677.pdf?locale=en_US&searchIndex=
13. Parrish, C., Waldbaum, B., Coleman, D., Blevins, C., Rodgers, K., Lee, B., Ober, C., Hudhud, L., Cox, S., Griffin, C., Chew, S., Chen, B., & Brock, M. (2020). Microwave Thermolysis Reduces Generalized and Social Anxiety in Young Adults With Axillary Hyperhidrosis. *Lasers in surgery and medicine,* 52(9), 842–847. https://doi.org/10.1002/lsm.23229
14. Stuart, M. E., Strite, S. A., & Gillard, K. K. (2020). A systematic evidence-based review of treatments for primary hyperhidrosis. *Journal of drug assessment*, *10*(1), 35–50. https://doi.org/10.1080/21556660.2020.1857149
15. Wade, R., Llewellyn, A., Jones-Diette, J., Wright, K., Rice, S., Layton, A. M., Levell, N. J., Craig, D., & Woolacott, N. (2018). Interventional management of hyperhidrosis in secondary care: a systematic review. *The British journal of dermatology*, *179*(3), 599–608. https://doi.org/10.1111/bjd.16558
16. Kaminaka, C., Mikita, N., Inaba, Y., Kunimoto, K., Okuhira, H., Jinnin, M., Kao, B., Tanino, R., Tanioka, K., Shimokawa, T., & Yamamoto, Y. (2019). Clinical and histological evaluation of a single high energy microwave treatment for primary axillary hyperhidrosis in Asians: A prospective, randomized, controlled, split-area comparative trial. *Lasers in surgery and medicine*, *51*(7), 592–599. https://doi.org/10.1002/lsm.23073
17. Hatano, T., Fukasawa, N., Miyano, C., Wiederkehr, I., & Miyawaki, T. (2021). Pathological Changes in Axillary Hyperhidrosis and Axillary Osmidrosis Induced by Microwave Treatment: Comparison of Single- and Double-Pass Irradiation. *Lasers in surgery and medicine*, *53*(9), 1220–1226.

https://doi.org/10.1002/lsm.23412
18. Lin, M. J., Dubin, D. P., Genece, J., Younessi, S., Rai, S., & Khorasani, H. (2021). A survey of long-term results with microwave energy device for treating axillary hyperhidrosis. *Journal of cosmetic and laser therapy : official publication of the European Society for Laser Dermatology*, *23*(3-4), 49–51. https://doi.org/10.1080/14764172.2021.1957115
19. Grove, G. L., Togsverd-Bo, K., Schwensen, J. F. B., Andersson, N. W., Nissen, C. V., Zachariae, C., & Haedersdal, M. (2023). Impact of microwave thermolysis energy levels on patient-reported outcomes for axillary hyperhidrosis and osmidrosis. *Lasers in surgery and medicine*, *55*(1), 105–115. https://doi.org/10.1002/lsm.23610
20. Chen, S. Q., Wang, T. T., Zhou, Y., Li, W., & Man, X. Y. (2022). Comparison of Long-Term Effectiveness and Safety of Microwave and Surgery in the Treatment of Axillary Osmidrosis: A Single-Center Retrospective Study. *Dermatologic surgery : official publication for American Society for Dermatologic Surgery [et al.]*, *48*(1), 126–130. https://doi.org/10.1097/DSS.0000000000003276
21. Wen, S., Unuma, K., Makino, Y., Mori, H., & Uemura, K. (2022). Fatal consequence after MiraDry® treatment: Necrotizing fasciitis complicated with streptococcal toxic shock syndrome. *Legal medicine (Tokyo, Japan)*, *58*, 102095. https://doi.org/10.1016/j.legalmed.2022.102095

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
08/29/2017	08/29/2017
08/29/2018	08/29/2018
08/28/2019	08/28/2019
08/26/2020	08/26/2020
07/22/2021	07/22/2021
07/26/2022	07/26/2022
06/26/2023	06/26/2023
06/25/2024	06/25/2024

*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. 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.