Policy Number	**MED201.050**
Policy Effective Date	**06/15/2025**
Policy End Date	**12/31/2025**

Transdermal Glomerular Filtration Rate

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

The use of the Transdermal Glomerular Filtration Rate Measurement System (TGFR) **is considered experimental, investigational and/or unproven**.

Policy Guidelines

None.

Description

The glomerular filtration rate (GFR) is a measurement that provides information about kidney function. Measuring GFR directly is considered the most accurate way to detect changes in kidney status, but measuring it is complicated and is typically performed only in research

settings and transplant centers. (1) Because of this, an estimated GFR calculated from formulas based on results of blood and urine tests are more commonly used.

Regulatory Status
The U.S. Food and Drug Administration (FDA) approved the MediBeacon Transdermal GFR (TGFR) (MediBeacon Inc., St. Louis, MO) system on January 17, 2025, through the premarket approval process (P230019). The TGFR system is a non-invasive way to assess kidney function in adults with normal or impaired kidney function. (3)

The TGFR System includes a small transdermal sensor, a display monitor, and Lumitrace® (relmapirazin) injection, a non-radioactive, non-iodinated fluorescent GFR tracer agent, which together allow assessment of kidney function by measuring the clearance rate of the fluorescent agent as it leaves the body. The system records Lumitrace fluorescence intensity transdermally as a function of time via a sensor placed on the skin. The TGFR Sensor records 2.5 fluorescent readings per second and the TGFR Monitor will provide clinicians with continuous, real-time measurement of GFR at the point of care, with no need for blood sampling or urine collection at the patient's bedside or in the outpatient setting. (2)

FDA product code: SDK

FDA documents note that the MediBeacon® TGFR is not approved for use in patients with GFR <15 ml/min/1.73 m^2, GFR >120 ml/min/1.73m^2, patients on dialysis, or anuric patients. The use of this device in patients with dynamic and rapidly changing renal function has not been validated. This device is not intended to diagnose acute kidney injury (AKI). (3)

Rationale

Medical policies assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Medical policies assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of this policy and credible information on technical reliability is available from other sources.

In a phase II pilot study authorized under an Investigation Device Exemption by the United States Food and Drug Administration, Dorshow et al. (2025) assessed the transdermal detection of the novel fluorescent GFR tracer agent relmapirazin in participants having normal or impaired kidney function across all human skin colors on the Fitzpatrick Skin Scale (FSS). This was a prospective, open study conducted at three clinical sites,

Washington University clinical research unit (St. Louis, MO), Saint Louis University clinical research unit (St. Louis, MO), and the Orlando Clinical Research Center (Orlando, FL). A total of 120 participants were enrolled, but the detachment of the source/detector module from the skin occurred in thirty participants during the 12-hour study, limiting the number of participants to 74 (age range 23 to 80 years). Participants had complete plasma GFR and transdermal GFR datasets. These participants spanned the range of kidney function from normal kidney function (120 to >60 mL/min/1.73m^2) to CKD Stage 3-4 kidney function (60 to 15 mL/min/1.73 m^2). Forty-six participants were FSS types I-III, and twenty-eight were FSS type IV-VI. A module containing an LED and photodetector to activate and collect transdermal relmapirazin fluorescence was attached adhesively to the upper chest of each participant. Relmapirazin (1.5mg/kg) was administered by intravenous push, and fluorescence emission was acquired for 12 hours. A two-compartment pharmacokinetic model fit the fluorescent intensity vs time data, and the fluorescence clearance rate (FCR) was extracted from the second (terminal) compartment. Plasma relmapirazin concentrations were measured contemporaneously and the corresponding plasma GFR for each participant was determined The fluorescence intensity as a function of time decreased to baseline for the participants with normal kidney function; however, in the participants with impaired kidney function, the 12-hour study was not long enough for complete elimination of the agent and return to baseline was not achieved. The FCR vs. the indexed plasma GFR yielded an excellent correlation over the range of GFR measured and for all skin colors with a $r^2 = 0.90$ (95% confidence interval, 0.85 to 0.94). No severe adverse events were reported. Although the data span the clinically relevant range of GFR and all the FSS skin tones, the sample size is limited. Another limitation due to sample size was that the algorithm developed to connect FCR with tGFR was accomplished without the training dataset/validation dataset model. Furthermore, possible interactions due to conditions of the skin such as in liver failure were not evaluated. (4)

UpToDate

An UpToDate review on "Assessment of kidney function" does not mention a transdermal system or fluorescent agent as management tools. (5)

A single published studies was identified that has evaluated the Transdermal GFR Measurement System (TGFR) for the evaluation of kidney function. It is currently being trialed for continuous, real-time measurement of GFR at the point of care. Due to the lack of evidence, the Transdermal GFR Measurement System (TGFR) is considered experimental, investigational and/or unproven.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this medical policy are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT03810833[a]	Tolerability and Background Fluorescence	12	Sept 2019

	of the MediBeacon Transdermal GFR Measurement System		
NCT05425719[a]	Pharmacokinetics and Safety of MB-102 (Relmapirazin) and the MediBeacon Transdermal GFR Measurement System in Evaluation of Kidney Function in Normal and Renal Compromised Subjects	249	Feb 2023
NCT05777174[a]	Study of MB-102 (Relmapirazin) and the Use of the MediBeacon® Transdermal GFR Measurement System Using the TGFR Reusable Sensor with Disposable Adhesive Ring	149	April 2024

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0602T, 0603T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

1. LabTests Online. Estimated glomerular filtration rate (eGFR) (Updated April 23, 2020). Available at <https://www.labtestsonline.org.uk> (accessed February 18, 2025).
2. MediBeacon - Transdermal GFR Measurement System (TGFR) Receives FDA Approval to Assess Kidney Function (Jan 2025). Available at <https://www.medibeacon.com> (accessed February 18, 2025).
3. FDA - Premarket Approval: MediBeacon® Transdermal GFR Measurement System (TGFR) (P230019). Food and Drug Administration - Center for Devices and Radiological Health (2025). Available at <https://www.accessdata.fda.gov> (accessed February 16, 2025).
4. Dorshow R, Debreczeny M, Goldstein S. Glomerular Filtration Rate Measurement Utilizing Transdermal Detection Methodology. Journal of the American Society of Nephrology. Feb 7, 2025.
5. Inker L, Perrone R. Assessment of kidney function. In: UpToDate, Sterns R (Ed), UpToDate,

Waltham, MA. Available at <https://www.uptodate.com> (accessed March 6, 2025).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
06/15/2025	Document updated with literature review. Coverage unchanged. Reference 3-5 added/others updated.
03/15/2024	Document updated with literature review. Coverage unchanged. No new references added.
03/15/2023	Reviewed. No changes.
04/15/2022	Document updated with literature review. Coverage unchanged. References updated.
02/15/2021	Reviewed. No changes.
09/15/2020	New medical document. The use of the Transdermal Glomerular Filtration Rate Measurement System (TGFR) is considered experimental, investigational and/or unproven.