Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.

Plan: AmeriHealth Caritas Pennsylvania and Keystone First	**Submission Date**: 11/1/2024
Policy Number: ccp.1428	**Effective Date:** 11/2019 **Revision Date:** October 1, 2024
Policy Name: Wearable dialysis and implantable artificial kidneys	

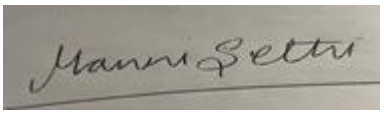
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☒ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Wearable dialysis and implantable artificial kidneys

Clinical Policy ID: CCP.1428

Recent review date: 10/2024

Next review date: 2/2026

Policy contains: Artificial kidney; implantable; wearable artificial kidney; hemodialysis.

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

Wearable dialysis and implantable artificial kidneys are investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Hemodialysis.
- Peritoneal dialysis.

Background

Hemodialysis is an established life-sustaining therapy for patients with end-stage kidney disease, but also inflicts a high burden on patients' quality of life in terms of time spent on dialysis, travel requirements, dietary and fluid restrictions, and job loss (Fissell, 2013; Stauss, 2023). Advances in peritoneal dialysis permit dialysis at home, but the requirements of three or four daily exchanges for continuous ambulatory therapy are lifestyle-limiting,

and overnight dialysis requires transport and storage of relatively large volumes of fresh dialysate. Neither modality can fully compensate for renal glomerular filtration and correct fluid and electrolyte imbalances, nor can they replace the complex endocrine, metabolic, and secretory functions of the renal tubules (van Gelder, 2018). As a result, waste products that are normally excreted rather than filtered by the kidney accumulate, resulting in uremic syndrome.

Technological advances to overcome these limitations focus on portable, wearable, and implantable versions that would allow patients to receive continuous renal replacement therapy while going on with normal daily life activities (Fissell, 2013). Ideally, such devices would achieve adequate solute clearances and ultrafiltration that would, in turn, accurately regulate electrolyte and acid-base status and blood pressure while permitting a normalized diet and fluid intake. They would need to be water efficient, lightweight (ideally less than five pounds), and ergonomically designed. The device would require a biocompatible dialysis membrane, a miniaturized battery-operated pumping system, dialysate regeneration, vascular access, safety features to prevent air emboli and blood loss, and patient monitoring capability.

A cross-sectional survey of 209 patients receiving nocturnal home hemodialysis and conventional hemodialysis identified several barriers to self-care dialysis: patient and caregiver competence with the technology, concerns over vascular access (e.g., needle phobia or undetected venous needle dislodgement), high costs, and infrastructure requirements for home dialysis (Cafazzo, 2009). The wearable artificial kidney may not fully address these concerns. The implantable artificial kidney is a biohybrid of artificial filters and living cells that could potentially lower some of the barriers to home dialysis and be accessible to a majority of patients requiring hemodialysis.

Regulation

The U.S. Food and Drug Administration has not approved any wearable or implantable artificial kidney devices for commercial use. However, in 2012, the Center for Devices and Radiological Health selected the Wearable Artificial Kidney (WAK™) (Blood Purification Technologies Inc., Beverly Hills, California) into its Innovation Pathway program that fast-tracks innovative technologies to market (U.S. Food and Drug Administration, 2016). Wearable kidney devices for hemodialysis and peritoneal dialysis include automated wearable artificial kidney/AWAK; hemodialysis/HD; carry life system/CLS; REcirculating DialYsis/REDY; Vicenza wearable artificial kidney/ViWAK; wearable artificial kidney/WEAKID; wearable ultrafiltration/WUF; and MiniKid (Groth, 2023; Stauss, 2023).

Findings

We included one evidence review for this policy produced by the Canadian Agency for Drugs and Technologies in Health (Topfer, 2016) and two narrative reviews of the state of the art in artificial kidney development (Castro, 2019; Jansen, 2014). Topfer (2016) identified three small pilot studies with the only published results in humans. One study from Italy (Gura, 2008) examined a wearable ultrafiltration device to treat fluid overload in six hospitalized participants with acute kidney injury. Two studies evaluated wearable dialysis worn for four to eight hours by adults with end-stage renal failure. One was conducted in the United Kingdom (n = 8 participants) (clinicaltrials.gov identifier NCT00454974; Davenport, 2007, 2011; Gura, 2009), and the other was a U.S. Food and Drug Administration-approved, proof-of-concept study (n = 7) from the United States (clinicaltrials.gov identifier NCT02280005; Gura, 2016). All received unfractionated heparin for anticoagulation. Participants using wearable dialysis had no dietary or fluid restrictions.

At this time, the clinical evidence is confined to proof-of-concept studies of early prototypes of the implantable artificial kidney and wearable ultrafiltration devices. Preliminary results from these studies suggest that wearable

dialysis is safe and feasible in achieving solute, electrolyte, and volume homeostasis. Serum electrolytes and hemoglobin remained stable over the treatment period, and fluid removal was consistent with prescribed ultrafiltration rates (Gura, 2016). Compared to conventional hemodialysis, the wearable artificial kidney produced mixed results with respect to two measures of middle molecule clearance, beta2-microglobulin and phosphate, which are analogous to other similar-sized molecules of waste (Davenport, 2011; Gura, 2009, 2016). The evidence supporting improvement in quality of life, which is a main objective of the technology, is lacking (Topfer, 2016).

In two studies (Davenport, 2007; Gura, 2016), participants reported greater satisfaction with the wearable device than with conventional hemodialysis, particularly in terms of convenience, freedom, fit with their lifestyle, reduced treatment-related side effects, and less discomfort during treatment. These devices have been designed to achieve small solute clearances for sustained periods and, theoretically, would have small solute clearances that are equivalent to that of continuous dialysis treatments in the intensive care setting.

As with conventional hemodialysis, wearable devices are prone to blood clot formation compromising vascular access (Davenport, 2007; Gura, 2008, 2016). Movement causing needle dislodgement can further compromise their performance. These authors noted that the safety mechanisms in these devices promptly alerted providers to venous needle disconnection or circuit clotting. Adverse events were generally mild and transient or treatable (e.g., mild hand or leg cramping and irregular heartbeat) with no signs of clinically significant hemolysis or cardiovascular changes. After addressing the technical problems, wearable dialysis may become a viable alternative to conventional hemodialysis, but larger and longer-term studies will be needed to confirm these results and provide evidence of improved quality of life and patient and caregiver preferences in the home setting to determine clinical viability.

The implantable artificial kidney holds promise for overcoming many of the shortcomings of self-care dialysis and donor-limited kidney transplantation, but its development is in the preclinical stages with no published results in humans other than for an early prototype wearable ultrafiltration device used to treat volume overload in patients with acute renal injury (Castro, 2019; Gura, 2008; Jansen, 2014; Topfer, 2016). The implantable artificial kidney represents the intersection of regenerative medicine and renal replacement therapy. It requires viable lines of renal proximal tubule epithelial cells and biocompatible membranes to replace essential renal functions, including active secretion of waste products. Technological refinements continue to focus on processes for incorporating stable cell models that remain functional during prolonged cultural timing, creating biocompatible membranes, and reducing device size without affecting functionality.

In 2020, we updated policy references. No policy changes are warranted.

In 2021, we added a pilot study in Singapore that examined the safety of the automated wearable artificial kidney device (Htay, 2022). Fifteen participants requiring peritoneal dialysis underwent up to nine automated wearable artificial kidney therapies over a 72-hour period and were followed for one month. No serious adverse events occurred, but 60% of participants developed abdominal pain or discomfort and 47% experienced a bloated feeling from the treatment. The authors recommended further device enhancements to improve ultrafiltration and reduce lesser adverse effects. No policy changes are warranted.

In 2022, we added a study addressing the challenge of removing urea from spent dialysate in wearable artificial kidneys. Authors concluded that electrooxidation, a technique that applies a current to the dialysate to convert urea into nitrogen, carbon dioxide, and hydrogen gas for dialysate regeneration, is not safe due to the generation of glucose degeneration products which are not biocompatible (van Gelder, 2021). No policy changes are warranted.

In 2023, we updated references. No policy changes are warranted.

In 2024, we found no new relevant literature. No policy changes are warranted.

References

On September 10, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Kidneys, Artificial” (MeSH), “Hemodialysis, Home/instrumentation” (MeSH), “Hemodialysis, Home/methods” (MeSH), and “wearable artificial kidney.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

9/2019: initial review date and clinical policy effective date: 11/2019

10/2020: Policy references updated.

10/2021: Policy references updated.

10/2022: Policy references updated.

10/2023: Policy references updated.

10/2024: Policy references updated.