group health Cooperative of eau claire	DEPARTMENT:	Utilization Management
	SUBJECT:	Experimental/Investigational
	PRODUCT LINE:	All
	POLICY NUMBER:	031
	ORIGINAL POLICY EFFECTIVE DATE:	06/20/20006
KMTSJ, Inc.	LAST REVISED DATE:	11/05/2020
	LAST REVIEWED DATE:	11/20/2024

SCOPE: To ensure Group Health Cooperative of Eau Claire (the Cooperative) handles requests for prior authorization in a manner consistent with member's policy specifications as well as state and federal regulations and according to evidence-based clinical practice guidelines and criteria.

POLICY: **Prior Authorization Required: YES**

It is the policy of the Cooperative to review both behavioral health and medical/surgical procedures and treatments that are new technologies and services that are potentially experimental/investigational through the prior authorization process and in conjunction with requesting provider and any supporting documentation provided. When there are questions related to experimental services, the Cooperative contacts a network provider to discuss and solicit feedback from the provider with expertise related to technology in question. New technologies are reviewed through the Cooperative's Benefit Committee and the review process is outlined in the New Technology Assessment policy.

The following evidence based clinical resources are used in the review of experimental/investigational services:

1. InterQual: evaluates medical necessity
2. Hayes, Inc.: Any medical service with a Hayes Rating (see below) of C, D1, D2 is considered experimental/investigational and would be considered a contract exclusion and denied.
3. National Clinical Practice Guidelines including but not limited to:
    a. National Comprehensive Cancer Network (NCCN)
    b. United States Preventive Services Taskforce Preventive Services Guidelines
    c. American College of Radiology Appropriateness Criteria
4. CMS National and Local Coverage Determinations

The Hayes Rating system reflects the strength and direction of the evidence regarding a medical technology And evaluates safety and efficacy, impact on health outcomes and patient management, indications for use, and patient selection criteria compared with the standard treatment/testing. Hayes Ratings are scaled A through D1 and D2 as follows:

Hayes Rating	Definition
A	**Established benefit.** Published evidence shows conclusively that safety and impact on health outcomes are comparable to or better than standard treatment/testing. Long-term safety and impact on health outcomes have been established, and other important questions concerning application of the technology have been answered. Drugs, biologics, and devices with an A rating have FDA approval, but not necessarily for the specific clinical application(s) under consideration.
B	**Some proven benefit.** Published evidence indicates that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, there are outstanding questions regarding long-term safety and impact on health outcomes, clinical indications, contraindications, optimal treatment/testing parameters, and/or effects in different patient subpopulations. Drugs, biologics, and

	devices with a B rating have FDA approval, but not necessarily for the specific clinical application(s) under consideration.
C	**Potential but unproven benefit.** Some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns.
D1	**No proven benefit.** Published evidence shows that the technology does not improve health outcomes or patient management for the reviewed application(s) or is unsafe.
D2	**Insufficient evidence.** There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management.

A service, procedure, or supply is considered **experimental/investigational** in the following (but not limited to the) situations below:

1. There is insufficient or inconclusive medical and scientific evidence to permit the Cooperative to evaluate the therapeutic value of the service, procedure, or supply requested
2. The services, procedures, or supplies requiring Federal of other governmental body approval, such as drugs and devices, do not have unrestricted market approval from the Food and Drug Administration (FDA) or final approval from any other governmental regulatory body for use in treatment of a specified condition
3. There is inconclusive medical and scientific evidence in peer-reviewed medical literature that the service, procedure, or supply has a beneficial effect on health outcomes
4. The service, procedure, or supply under consideration is not as beneficial as any established alternatives
5. There is insufficient information or inconclusive scientific evidence that, when used in a non-investigational setting, the service, procedure, or supply has a beneficial effect on health outcomes or is as beneficial as any established alternatives
6. Hayes C or D rating

The Cooperative compared strategies, processes, evidentiary standards and source information used to evaluate experimental/investigational services. In compliance with Mental Health Parity and Equity Act, processes used to evaluate and determine whether mental health/substance use disorder services are experimental/investigational are comparable to, and applied no more stringently, than the processes used to evaluate and determine whether medical/surgical services are experimental/investigational. The plan uses the same definitions for experimental/investigational services for both mental health/substance use disorder and medical/surgical services as defined in plan documents. Mental health/substance use disorder coverage determinations about experimental/investigational services are not made any differently than medical/surgical coverage determinations. Policies and criteria based on evidence based clinical practice guidelines are used for both mental health/substance use disorder coverage decisions and medical/surgical coverage decisions. Clinic policies related to coverage determinations are developed with the same standards and not applied any more stringently to mental health/substance use disorder services.

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APPROVED: Michele Bauer MD DATE: 11/20/2024

Formal policies and procedures require department manager review, approval and signature. Executive and/or administrative policies and procedures require CEO/General Manager review, approval and signature.

REVISION HISTORY:

Rev. Date	Revised By/Title	Summary of Revision
02/25/2013	Carol E. Ebel, RN HM	This is a continuation of the archived P & P.
02/15/2014	Lynne Komanec, RN HM Manager	Reviewed with no changes
01/12/2015	Betsy Kelly, RN	Rewritten to reflect updates.
04/22/2016	Betsy Kelly, RN	Reviewed with no changes.
04/25/2017	Michele Bauer, MD	Reviewed with no changes.
04/26/2018	Michele Bauer, MD	Added Hayes Rating Scale
04/28/2020	Michele Bauer, MD	Reviewed. No changes.
10/07/2020	Michele Bauer, MD	Added definition of when services would be considered E/I
11/05/2020	Michele Bauer, MD	Updated to reflect network physician involvement
11/05/2021	Michele Bauer, MD, CMO	Updated to include New Technology Assessment policy
11/10/2022	Michele Bauer, MD, CMO	Reviewed. No changes.
11/14/2023	Michele Bauer, MD, CMO	Reviewed. No changes.
11/20/2024	Michele Bauer, MD, CMO	Added mental health parity language.