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New Technology Assessment

Description

Technology assessments are a structured analysis of a technology, drug or treatment performed to provide input to clinical policy. Technology assessments include examining safety, efficacy, feasibility outside the investigational setting, comparability to existing technologies relative to outcomes, indications for use, and ethical implications and consequences. Technology assessments are comprehensive and are firmly based on research, clinical evidence and application of the scientific method.

Strategy

The Technology Assessment Committee (including Plan Medical Directors and Registered Nurses [RN]) use the five Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria listed below to assess new and evolving technology. Within a structured framework, the Technology Assessment Committee (TAC) conducts an independent and unbiased assessment of the new or emerging technology.

The assessment process includes an analysis of the condition or illness and available treatments for which the new or emerging technology is intended. Research regarding the benefits, risk and health outcomes from the available clinical data and other information submitted by the interested physician, organization or vendor is considered by the committee. The TAC reviews scientific evidence and outcomes from randomized control trials, observational studies and safety surveillance. The TAC's decisions help protect against the use of treatments, devices and medications that are not proven or not safe.

Process

Requests to cover new technologies may be received by a variety of CareFirst departments including but not limited to: Provider or Member Services, Health Services, Government Affairs, Special Investigations Unit and/or Legal. Submitters may include providers (internal or external), members or the healthcare technology industry. CareFirst may also identify a new technology during routine clinical research or during medical policy review.

CareFirst does not limit or restrict who can submit a request to the TAC for review of new or emerging technology. There is no limit on the number of mental health and substance use disorder (MH/SUD) or medical services (M/S) requests that can be submitted and received by the TAC. A request may be submitted by any provider, vendor, interested organization, a representative from the legislative community, a CareFirst Medical Director or an internal CareFirst department who has experience or knowledge regarding new or emerging treatment.

When a new technology is identified, the below process is followed:

Research

The technology is assigned to a qualified healthcare policy associate who coordinates the collection



of supporting documentation including a description of the technology, the practical value the technology provides, the population affected, potential economic impact, applicable diagnoses, procedure codes and supporting literature.

The qualified healthcare policy clinical associate is responsible for assessing and documenting the qualifications and credentials of specialty consultants or subject matter experts engaged in the technology assessment process. The technology review begins with a comprehensive review of the current body of evidence and data outcomes.

A review determines if the technology is subject to approval by U.S. government regulators, such as the Food and Drug Administration (FDA). If so, information is gathered about the status of regulatory approval.

Online resources such as [Hayes Technology Inc.](#), [the Cochrane Library](#), [the Centers for Medicare & Medicaid Services](#) and [the National Institute of Health—U.S. National Library of Medicine](#) are consulted for study abstracts and articles related to the technology in question. The literature supporting the technology is evaluated based on the merit of the scientific evidence.

CareFirst considers randomized, double-blinded, controlled trials to be most credible source of evidence, followed by non-randomized and/or non-controlled trials, meta-analysis, case series, case studies, individual case reports, and individual or consensus opinion.

Other considerations for evaluating the scientific evidence include the number of subjects, patient selection criteria, homogeneity of the study group, measurement criteria, follow-up periods, complicating factors, dropout rates and possible conflicts of interest.

CareFirst also considers input from physicians and other recognized experts who are:

- not employees of CareFirst,
- are currently treating patients for the disease being evaluated,
- are board-certified in the specialty or subspecialty of the disease or condition being evaluated,
- or are generally recognized by their peers as being authoritative resources as evidenced by:
 - faculty appointments,
 - authorship of a significant body of peer-reviewed literature in the pertinent specialty,
 - a demonstrated history in leadership in local, State, or National professional associations and non-profit patient and community organizations that address the disease in question,
 - or have a demonstrated history of substantial experience and practical knowledge in the specialty or subspecialty in question.

Specialty consultants, local providers outside of CareFirst and/or subject matter experts in the field are called upon to offer guidance or an opinion regarding whether enough scientific studies were completed to establish safety and efficacy. CareFirst may utilize independent review organizations (IRO) for unbiased opinions from board-certified practitioners who have a demonstrated history of substantial experience and knowledge. These consultants are board-certified in the specialty or subspecialty of the disease, condition, device or technology being evaluated. If the technology is extremely complex, it may be reviewed by experts in academic and medical institutions.

These practitioners offer insight based on their current patient experience, studies or publications. They assist CareFirst with evaluating the quality of the technology and describe how other payors have adopted the technology. Disclosures are requested of all physicians or subject matter experts. The opinions of our consultants are considered tools in the evaluation process and are not binding



for acceptance or rejection of a technology. Further research includes comparison to BlueCross BlueShield Association (BCBSA) criteria used to evaluate technology.

The criteria applied is as follows:

- the technology must have final approval from the appropriate U.S. government regulatory bodies and
- the scientific evidence must permit conclusions concerning the effect of the technology on health outcomes and
- the technology must improve the net health outcome and
- the technology must be as beneficial as any established alternatives and
- the improvement must be attainable outside the investigational settings.

Technology Review Process

The technology information is summarized based on the expert review, scientific literature and an analysis of how the technology compares to the BCBSA's five evaluation criteria. This document is shared with the TAC participants a week prior to the meeting.

Members of the TAC include CareFirst's Vice President/Chief Medical Officer or designee, Medical Directors, Behavioral Health Medical Director, Healthcare Policy team members and other Health Services associates with clinical experience.

CareFirst requires participation of a local specialist with knowledge and current experience relevant to the technology being presented when such expertise is warranted.

The committee meets six times per year and as needed.

During the meeting, a healthcare professional or a company in the healthcare technology industry may present the key technology features, the research methodology and the study results. The TAC evaluates all research used to test the validity and reliability of each technology to reach an evidenced-based decision.

Decision

The Chief Medical Officer or designee and Medical Directors determine if the clinical benefits of the technology warrant approval and how the technology will be integrated into the existing member benefit structure. CareFirst's decision to provide coverage for an emerging medical or surgical treatment shall result from the consensus opinion from CareFirst's analysis and the knowledge provided to CareFirst by clinical experts.

For approved technology, a draft medical policy is developed by CareFirst in conjunction with the clinical experts consulted previously. This draft medical policy decides the patient selection criteria for an emerging medical or surgical treatment for which coverage by the carrier is to be provided. The draft medical policy is introduced to the Medical Policy Committee for comments. If warranted, the policy will be reviewed by Legal prior to final approval by the Chief Medical Officer or designee. Approved medical policies are publicly released and available on carefirst.com. Provider notification occurs via the CareFirst provider newsletter. The healthcare professional or the company is notified of non-approval. The decision is recorded in the TAC meeting minutes and archived or flagged for future review.



Unapproved services will be deemed not medically necessary or experimental and investigational. If not medically necessary, they may be flagged for continued monitoring for evolving information. If deemed experimental or investigational, they will be flagged for routine review in 24 months.

Out of Scope

Services that are excluded from the benefit plan would not be in-scope for TAC review.

Services must be performed by a clinical professional with licensure to be considered for TAC review.

Services already deemed experimental and investigational would be reviewed as part of regular medical policy review outside of TAC. However, a change in technology may direct this review to TAC and if so, it would be reviewed.

Framework

Status	Definition	Outcome
Meets criteria 1-5	<p><u>Technology is beneficial:</u> There is sufficient published clinical evidence to support the safety, efficacy and medical necessity of the technology for specific indications and conditions. There may be clinical criteria that must be met and/or available alternate technology.</p> <p><u>Criteria 1-5:</u></p> <ul style="list-style-type: none"> • The technology yields an improvement in health outcomes as detailed in the clinical evidence. • When compared to alternative treatments, health outcomes are improved with use of the new technology, as detailed in the clinical evidence. • Technology has approval from the appropriate U.S government and/or regulatory bodies. • Benefits of the proposed technology outweigh harmful effects. • Improvements are attainable outside of the investigational setting. 	<ul style="list-style-type: none"> • Medical policy developed and/or revised. • The evidence reveals that the technology meets the standard of care. • Proven medically necessary technology, however prior authorization may be required, and the Medical Policy may list clinical indications with specific criteria that must be met for coverage.
Does not meet criteria 1-5	<p><u>Technology has no benefit or is determined to be unsafe or ineffective:</u> Research has determined that there is not sufficient clinical evidence to support the technology or the clinical evidence has led to a conclusion that the proposed technology is unsafe or ineffective.</p>	<ul style="list-style-type: none"> • Technology is determined to be experimental investigational. • A new medical policy may be developed, or an existing medical policy may be reviewed and revised during



Status	Definition	Outcome
		the periodic review process.
Insufficient Clinical Evidence	<u>Technology is unproven:</u> There is not sufficient clinical evidence to support the technology.	<ul style="list-style-type: none"> • Will continue to analyze the data, including but not limited to prior authorization request, claim utilization and the appeal experience. • Periodically reassess the technology for coverage indications. • A medical policy will not be developed.

Qualifications of individuals evaluating new technologies

Technology assessment is a method by which new, emerging or current technologies are thoroughly researched. Healthcare Policy is a business unit within the CareFirst Health Service division responsible for coordinating the medical policy review process. This business unit is comprised of RNs with Bachelor's degrees in nursing or healthcare-related fields and experience in various clinical and research settings. All Healthcare Policy Associates are required to obtain their Certified Professional Coder (CPC) certification from the American Academy of Professional Coders. Healthcare Policy conducts the technology assessment and oversees the TAC.

The TAC provides a forum in which evidence is evaluated to determine whether a procedure, technique, drug or device will be covered by CareFirst. The TAC is comprised of the Plan's Medical Directors, associates of the Healthcare Policy Department and other members of the Health Services division. The committee includes a CareFirst Medical Director who is a Psychiatrist with over 30 years of experience providing care to patients with MH/SUD. This physician is also board-certified by the American Board of Psychiatry & Neurology.

In addition, the Director of Behavioral Health is a Licensed Clinical Professional Counselor, with a Master of Arts in Counseling Psychology and 17 years of experience treating patients in various inpatient and outpatient settings. Other committee participants' titles, role and qualifications are listed below.

CareFirst Title	Qualifications
Vice President, Senior Medical Director	Medical degree in primary care specialty from an accredited medical school and an American residency in a primary care specialty. Five years of clinical experience and five years of administrative experience in a managed care setting. Current medical license and board certification in Maryland, Washington, D.C. and Virginia without restriction and board certification. Previous experience as Medical Director for a healthcare company.



CareFirst Title	Qualifications
CareFirst Medical Director	Medical degree from an accredited medical school, completion of an American residency program required with postgraduate training, eight years of clinical practice experience, and three years of care management experience. Board certifications of current Medical Directors include internal medicine, pediatrics, obstetrics and gynecology, family medicine, general dentistry, orthodontist and periodontist.
CareFirst Medical Director, Behavioral Health	Medical degree from an accredited medical school, completion of an American residency program, minimum of five years of clinical practice experience in the field of psychiatry and two years of managed care experience with accreditation experience. Board certification includes American Board of Psychiatry & Neurology.
Medical Review and Appeals Director	Bachelor's degree in nursing, eight years of clinical experience in care management, three years of experience leading in a managed care or health insurance environment with a focus on clinical medical review and appeals and grievances.
Utilization Director	Bachelor's degree in nursing, eight years of clinical and/or utilization review experience and three years of management experience.
Behavioral Health Services Director	Master's degree in mental health can be in one or more of the following areas: social work, psychology, nursing or counseling. Eight years of post-Master's clinical behavioral health/psychiatric experience with three years of management experience or licensed clinical professional counselor and Master's in counseling psychology.
Dental Director	Medical degree in dentistry and eight years of experience in dental health or medical management and three years of management experience.
Healthcare Policy Manager	Bachelor's degree in nursing or other health-related discipline, five years of experience in a health insurance environment, with focus on policy development and implementation and/or claims operations/medical review experience. Three years supervisory experience or demonstrated progressive leadership experience.
Lead Medical Policy Analyst	Bachelor's degree in nursing or healthcare-related field, eight years of varied clinical experience in a healthcare setting and five years of experience with a healthcare payor organization.
Senior Medical Policy Analyst	Bachelor's degree in nursing and five years of varied clinical nursing experience in a healthcare setting.



CareFirst Title	Qualifications
Lead Clinical Appeals Nurse	Five years of medical-surgical or similar clinical experience, three years of experience in clinical appeals and analysis unit with one year as a Senior Appeals Specialist. BSN/MSN degree, one to two years of experience in a CareFirst Care Management/Health Services Program.
Clinical Medical Review Supervisor	Five years of acute clinical experience, previous case management, discharge planning or utilization review experience, and three years of Clinical Review Nurse in the clinical medical review area. BSN/MSN Degree and one to two years of experience in a CareFirst Care Management/Health Services Program.
Lead Clinical Medical Review Nurse	Five years of acute clinical experience, previous case management, discharge planning or utilization review experience, and three years of Clinical Review Nurse in the clinical medical review area. BSN/MSN Degree and one to two years of experience in a CareFirst Care Management/Health Services Program.
Senior Medical Coding Specialist	Five years of experience in risk-adjustment coding, ambulatory coding and/or CRC coding and experience in managed care, state or federal health care programs or health insurance industry experience. CCS-Certified Coding Specialist, Certified Coder (CCS or CPC)-AHIMA or AAPC.
Utilization Management Specialist	Five years of acute clinical experience, previous case management, discharge planning or utilization review experience, and three years of clinical nursing experience. BSN/MSN Degree and one to two years of experience in a CareFirst Care Management/Health Services Program.

CareFirst also considers input from physicians and other recognized experts who are not employees of CareFirst and:

- are currently treating patients for the disease or condition being evaluated and/or
- are board-certified in the pertinent specialty or subspecialty area of the disease or condition being evaluated and/or
- are generally recognized by their peers to be authoritative resources in the clinical area being evaluated as evidence by:
 - faculty appointments and/or
 - authorship of a significant body of peer-reviewed clinical literature in the pertinent specialty area and/or
 - a demonstrated history of leadership in local, state or national professional associations and nonprofit patient and community advocacy organizations that address the disease or condition and the specialty or subspecialty area in question and/or
 - have a demonstrated history of substantial experience and practical knowledge in the specialty or subspecialty area in question.

Applicable Benefit Classifications: inpatient in-network, inpatient out-of-network, outpatient in-network, outpatient out-of-network, emergency care and prescription drugs.



Factor 1		Clinical Evidence
Definition	A member, provider or other submits clinical evidence or new evidence identified during routine clinical research or medical policy review.	
Evidentiary Standards	<ul style="list-style-type: none"> • Clinical evidence (scientifically based) can come from: <ul style="list-style-type: none"> ○ FDA ○ Hayes ○ Cochrane Library ○ Centers for Medicare & Medicaid Services ○ National Institute of Health—U.S. National Library of Medicine ○ MCG, ACG, LCDs, NCDs ○ NCCN ○ PubMed ○ UpToDate • Peer-reviewed literature • Systematic reviews • Trials (randomized, controlled) • Studies (comparative, cohort, cross-sectional, retrospective, surveillance) • Case reviews • Editorials • Professional and association opinions 	

Factor 2		Meets New Technology Criteria
Definition	<ul style="list-style-type: none"> • The new technology meets the established criteria. • The technology yields an improvement in health outcomes as detailed in the clinical evidence. • When compared to alternative treatments, health outcomes are improved with use of the new technology, as detailed in the clinical evidence. • Technology has approval from the appropriate U.S government and/or regulatory bodies. • Benefits of the proposed technology outweigh harmful effects. • Improvements are attainable outside of the investigational setting. 	
Evidentiary Standards	<ul style="list-style-type: none"> • Clinical evidence (scientifically based) can come from: <ul style="list-style-type: none"> ○ FDA ○ Hayes ○ Cochrane Library ○ Centers for Medicare & Medicaid Services ○ National Institute of Health—U.S. National Library of Medicine ○ MCG, ACG, LCDs, NCDs ○ NCCN ○ PubMed 	

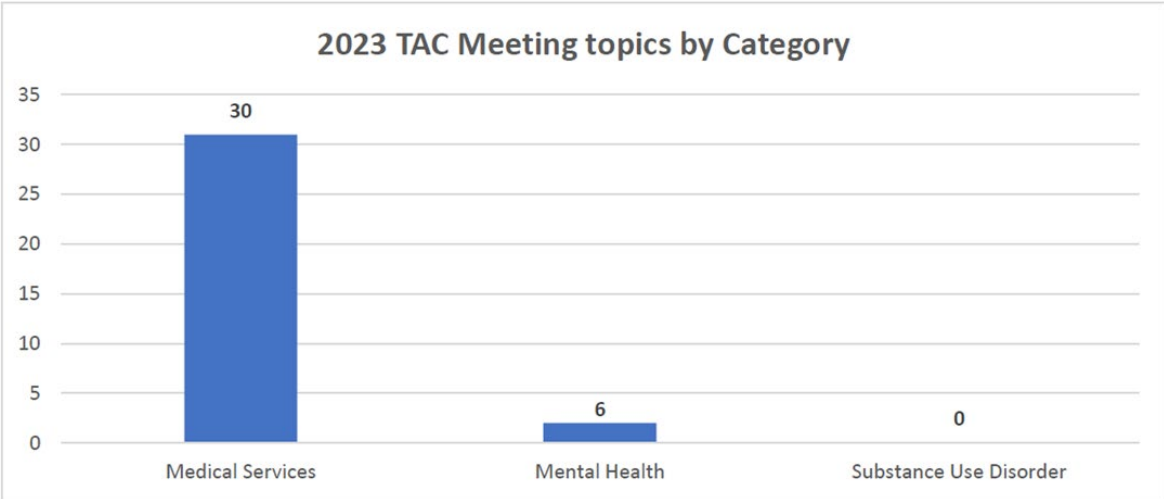


- UpToDate
- Peer-reviewed literature
- Systematic reviews
- Trials (randomized, controlled)
- Studies (comparative, cohort, cross-sectional, retrospective, surveillance)
- Case reviews
- Editorials
- Professional and association opinions

Additional Operational Information:

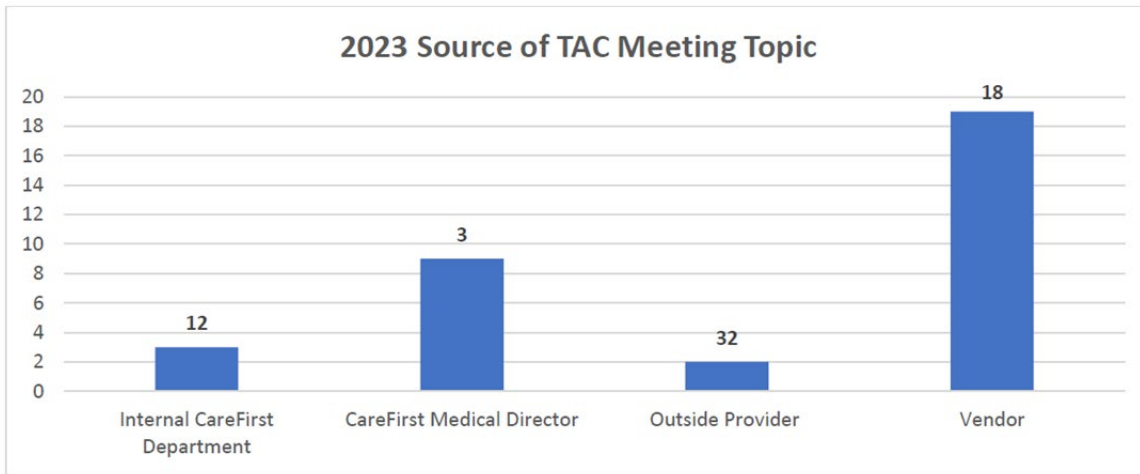
In the 2023 plan year, 36 topics were discussed at TAC meetings. The chart below illustrates the volume of topics broken down by M/S and MH/SUD. 83.3% of all meeting topics were related to M/S and 16.7% represented topics outlining mental health technologies. There was no available substance use disorder technologies for review in 2023.

2023 MHPAEA Technology Reporting for NQTL

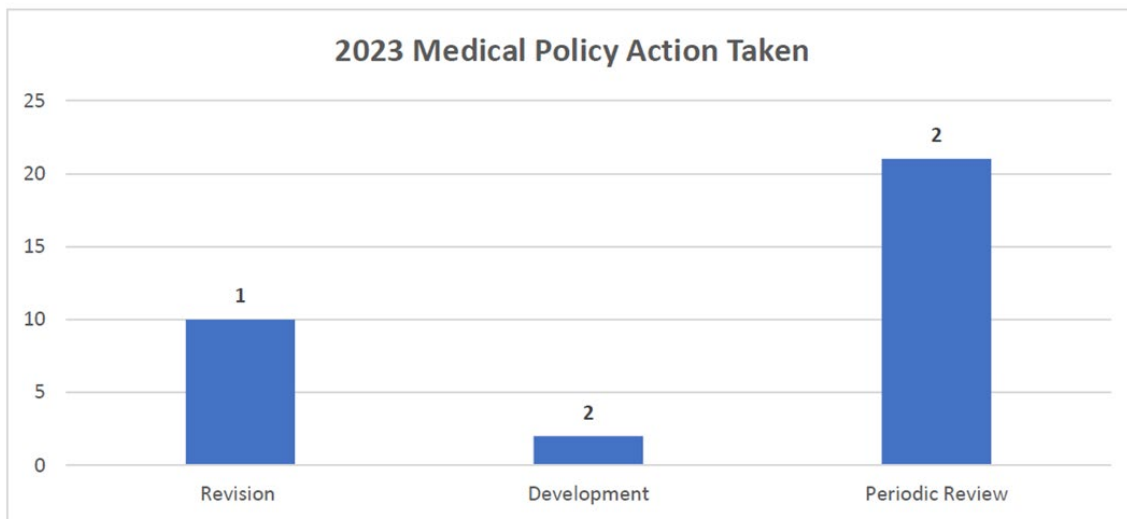


The chart below illustrates the sources in which topics were received by Healthcare Policy and represent internal CareFirst departments, CareFirst Medical Director recommendations, outside providers and vendors. There were six topics received for mental health, one via a Medical Director recommendation, two from internal CareFirst departments and the remaining three were received from vendors.





Based on the analysis of the 2023 data, there were a total of five TAC topics related to medical services that resulted in actions to policy, hence presentations were given at the Medical Policy Committee. This volume represented 13.9% of the total volume of topic reviewed by then TAC. There were no medical policy impacts related to mental health topics.



The above graph outlines the CareFirst coverage decisions based on the review of all topics presented to the TAC in 2023. Of the 36 topics presented, the six topics brought were related to mental health treatment and included:

- Prescription digital therapeutic
- Pharmacogenomic testing of medication selection for Major Depressive Disorder
- Digital therapeutic specific to Post Traumatic Stress Disorder (PTSD) and Panic Disorder
- EndeavorRX application to be used in conjunction with additional treatment for Attention Deficit Hyperactivity Disorder (ADHD)
- Continuous in-person monitoring and intervention (e.g., psychotherapy, crisis intervention), as needed during psychedelic medication therapy
- SPRAVATO® (Esketamine)

The outcome of the review was as following:



- **reSET Prescription Digital Therapeutic used for Psychiatric Disorders:** Based on an assessment conducted by an independent review organization, the technology is still an investigational approach for treatment and the impact reSET computerized behavioral therapy device on patients beyond 12 weeks has not been studied. With this assessment, the technology is deemed experimental/investigational.
- **Pharmacogenomic testing of medication selection for Major Depressive Disorder:** Due to clinical utility, the decision was made to remove the exemption from vendor utilization review and render a medically necessary coverage decision.
- **Digital therapeutic specific to PTSD and Panic Disorder:** Based on an assessment conducted by an independent review organization, the evidence supporting the efficacy of the device was not solidified. The quality of the clinical study was not sufficient, as it lacked a control group and did not possess a randomized design, nor demonstrated efficacy as an established alternative of adjunctive pharmaceutical and/or non-pharmaceutical treatment. The results of the assessment rendered an experimental/investigational coverage decision.
- **EndeavorRX application to be used in conjunction with additional treatment for ADHD:** Limited literature and research that lacked qualitative results on the impacts of the therapeutic on patients with ADHD. Therefore, it was deemed experimental/investigational.
- **Continuous in-person monitoring and intervention (e.g., psychotherapy, crisis intervention), as needed during psychedelic medication therapy:** Psychedelic medication therapy is an emerging field, as the effective date of the services was 01/01/2024 and limited evidence has proven treatment efficacy. The services were deemed experimental/investigational.
- **SPRAVATO® (Esketamine) for Treatment of Resistant Major Depressive Disorder:** Based on research conducted, the studies that support SPRAVATO® have compared antidepressant-only treatment groups against treatment groups of a combination of SPRAVATO® and antidepressant. The combination treatment was at least as effective as treatment using only an antidepressant. Additionally, clinician judgment of suicide risk was also assessed. Secondary endpoints included Montgomery-Åsberg Depression Rating Scale (MADRS) score and clinician assessment at 24 hours and day 25 post-baseline. Subsequently, group reductions in clinician global judgment of suicide risk scores were not statistically different at any time point. The treatment was deemed experimental/investigational.

NOTE: While not discussed by the TAC, through collaboration with Behavioral Health Director, Medical Policy 3.01.015—Autism Spectrum Disorders (ASD) was revised to provide guidelines associated with the developmental relationship-based intervention (DRBI) approach.

Requests for assessment of new technology are prioritized based on clinical need, legislative demands and impact to CareFirst members. Technologies with support from local physicians that have shown strong clinical validity are prioritized for review. All requests are directed to a qualified Healthcare Policy Clinical Associate, who coordinates the collection of supporting documentation including a description of the technology, the practical value the technology provides, the population affected, potential economic impact, applicable diagnoses and procedure codes, and supporting literature. The qualified Clinical Associate is responsible for assessing and documenting the qualifications and credentials of specialty consultants or subject matter experts engaged in the Technology Assessment process.



Experimental/Investigational Determinations

Description

The Experimental, Investigational and Unproven (EIU) designation is used to describe services, drugs or technologies that are excluded from coverage because they are not consistent with evidence-based clinical standards. In not being consistent with evidence-based clinical standards, clinical evidence supports that the services, drugs or technology are ineffective, unproven or unsafe for the condition being treated.

Strategy

CareFirst excludes coverage of services, drugs and technologies that are determined to be EIU based on clinical policy and plan documents. Services, drugs or technology identified as EIU have been determined to not be clinically effective or safe for the condition being treated. CareFirst develops clinical policy for services, drugs and technology using scientifically based clinical evidence and sources.

Process

CareFirst uses committees to assess services, drugs and technology using scientifically based clinical evidence and peer-reviewed literature, in addition to a hierarchy of evidence. The clinical evidence is used to update clinical policy for M/S and MH/SUD. Healthcare Policy Associates are responsible for gathering clinical evidence. The Medical Policy Committee reviews the clinical evidence and renders a determination. The Medical Policy Committee contains membership including M/S and MH/SUD Medical Directors, RNs and medical policy and claims specialists. Once a determination has been rendered, clinical policy is updated, including the Medical Policy Committee’s findings. New clinical policies are developed as needed. All clinical policies (M/S and MH/SUD) are reviewed at least every two years, or sooner as clinical evidence becomes available.

Applicable Benefit Classifications: inpatient in-network, inpatient out-of-network, outpatient in-network, outpatient out-of-network, emergency care and prescription drugs.

Factor 1	Clinical Evidence
Definition	A member, provider or other submits clinical evidence or new evidence identified during routine clinical research or medical policy review.
Evidentiary Standards	<ul style="list-style-type: none"> • Clinical evidence (scientifically based) can come from: <ul style="list-style-type: none"> ○ FDA ○ Hayes ○ Cochrane Library ○ Centers for Medicare & Medicaid Services ○ National Institute of Health U.S. National Library of Medicine ○ MCG, ACG, LCDs, NCDs ○ NCCN ○ PubMed ○ UpToDate



	<ul style="list-style-type: none"> • Peer-reviewed literature • Systematic reviews • Trials (randomized, controlled) • Studies (comparative, cohort, cross-sectional, retrospective, surveillance) • Case reviews • Editorials • Professional and association opinions
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Factor 2	Meets New Technology Criteria
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Definition	<ul style="list-style-type: none"> • The new technology meets the established criteria. • The technology yields an improvement in health outcomes as detailed in the clinical evidence. • When compared to alternative treatments, health outcomes are improved with use of the new technology, as detailed in the clinical evidence. • Technology has approval from the appropriate U.S government and/or regulatory bodies. • Benefits of the proposed technology outweigh harmful effects. • Improvements are attainable outside of the investigational setting.
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Evidentiary Standards	<ul style="list-style-type: none"> • Clinical evidence (scientifically based) can include: <ul style="list-style-type: none"> ○ FDA ○ Hayes ○ Cochrane Library ○ Centers for Medicare & Medicaid Services ○ National Institute of Health U.S. National Library of Medicine ○ MCG, ACG, LCDs, NCDs ○ NCCN ○ PubMed ○ UpToDate • Peer-reviewed literature • Systematic reviews • Trials (randomized, controlled) • Studies (comparative, cohort, cross-sectional, retrospective, surveillance) • Case reviews • Editorials • Professional and association opinions
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Treatment Plan Requirements

Refer to your plan documents to determine if this NQTL is applied to your plan.



Description

Treatment plans may be used when consistent with evidence-based clinical guidelines to help support optimum clinical outcomes.

Strategy

CareFirst requires that providers maintain treatment plans as clinically indicated, for some M/S services. For MH/SUD services, providers are only required to maintain treatment plans for Applied Behavioral Analysis (ABA), as indicated by state guidance pertaining to the medical management of services and clinical guidelines specific to ABA services.

Process

When appropriate, providers may be asked to maintain treatment plans including the goals of treatment, patient progress and coordination of care. When submitting requests for services that require authorization, providers include clinical information relevant to the request. For services with treatment plans, the treatment plan is an essential part of relevant clinical information.

Applicable Benefit Classifications: outpatient in-network and outpatient out-of-network.

Refer to your plan documents and/or contracts to determine what services this NQTL is applied to. Below is a generic list.

Applicable Services M/S: durable medical equipment, rehabilitative services, radiology services and surgery

Applicable Services MH/SUD: ABA therapy

Factor 1	Supports Optimal Clinical Outcomes
Definition	The application of a treatment plan supports optimal clinical outcomes as determined by internal clinical experts based on evidence-based guidelines.
Evidentiary Standards	<ul style="list-style-type: none">• Clinical evidence (scientifically based) can include:<ul style="list-style-type: none">○ FDA○ Hayes○ Cochrane Library○ Centers for Medicare & Medicaid Services○ National Institute of Health U.S. National Library of Medicine○ MCG, ACG, LCDs, NCDs○ NCCN○ PubMed○ UpToDate• Peer-reviewed literature• Systematic reviews• Trials (randomized, controlled)• Studies (comparative, cohort, cross-sectional, retrospective, surveillance)



	<ul style="list-style-type: none"> • Case reviews • Editorials • Professional and association opinions
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Factor 2 State Guidance	
Definition	The states guidance regarding the medical management of services.
Evidentiary Standards	State guidelines



Utilization Management NQTLs

Medical Necessity

Description

Medical necessity means healthcare services or supplies that a healthcare provider, exercising prudent clinical judgment, renders to or recommends for a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms.

These healthcare services or supplies are:

- In accordance with generally accepted standards of medical practice
- Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for a patient's illness, injury or disease
- Not primarily for the convenience of a patient or healthcare provider
- Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results in the diagnosis or treatment of that patient's illness, injury or disease

Strategy

CareFirst uses internal clinical policy (CareFirst Medical Policy Reference Manual) for M/S and MH/SUD, which is drafted using external clinical criteria, in addition to peer-reviewed literature, clinical trials, professional opinion and publications by professional societies or government agencies. If the internal criteria are not sufficient to render a medical necessity approval determination, then external clinical criteria will be used.

CareFirst uses appropriate, evidence-based external clinical criteria for M/S and MH/SUD benefits. These include:

- The Modified Appropriateness Evaluation Protocol (AEP) Criteria (for M/S inpatient)
- The Apollo Managed Care Physical Therapy (for Physical Therapy)
- Occupational Therapy, Speech Therapy and Rehabilitation Criteria (for OT, ST, and Rehabilitation)
- MCG Guidelines 25th edition (for Behavioral Health, Ambulatory Care, Inpatient & Surgical Care, and Home Care)
- The American Society of Addiction Medicine (ASAM) criteria (for SUD)

Process

All CareFirst M/S and MH/SUD policies in the CareFirst Medical Policy Reference Manual are developed based on the most recent clinical evidence and peer-reviewed literature. Policies are reviewed by CareFirst's Chief Medical Officer, Senior Medical Directors, and the Behavioral Health Medical Director. The criteria are always used with an assessment of the individual patient's needs. CareFirst's medical and behavioral health policies are available on the web at carefirst.com.



The internal and external criteria used for both M/S and MH/SUD are authorized by the CareFirst Criteria Review Committee. Internal criteria are reviewed annually and updated as needed to reflect current patterns of care. Input and suggestions are actively invited and sought from stakeholders, such as community physicians, primary care providers and behavioral health practitioners. Specialists are consulted when specialist input is needed for both M/S and MH/SUD.

For M/S and MH/SUD benefits, appropriately qualified clinical staff make medical necessity determinations. Approvers require an active RN license in Maryland, Washington, D.C. or Virginia with a minimum of 7–10 years of clinical experience or actively Licensed Clinical Social Worker (LCSW) or Licensed Certified Social Worker-Clinical (LCSW-C) or Licensed Certified Professional Counselor (LCPC) and must have a minimum of 7–10 years of clinical experience. For both M/S and MH/SUD, denials may only be issued by Medical Directors, with an MD degree in addition to 5 years clinical experience. A psychiatric MD degree and 5 years clinical experience is required for MH/SUD clinical denials.

Applicable Benefit Classifications: inpatient in-network, inpatient out-of-network, outpatient in-network, outpatient out-of-network, emergency care and prescription drugs.

Factor 1		Generally Accepted Standards of Medical Practice
Definition	Standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations and views of healthcare providers practicing in relevant clinical areas, and any other relevant factors. CareFirst uses appropriate criteria based on the service type to determine generally accepted practice standards. The process does not differ from M/S or MH/SUD, though appropriate criteria are applied to its corresponding service type. There is no specific threshold as this follows standard guidelines and professional recommendations.	
Evidentiary Standards	<ul style="list-style-type: none"> • MCG care guidelines • ACOG recommendations • AAP recommendations • US Preventative Task Force • Evidence-based recommendations • CMS national and local coverage determinations • Apollo Managed Care guidelines • NIA Magellan recommendations • Peer-reviewed medical literature • ASAM criteria for SUD services 	

Factor 2		Clinically Appropriate
Definition	The service must be clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease. The service must be clinically appropriate and effective per the accepted guidelines based upon the patient's condition.	



Evidentiary Standards	<ul style="list-style-type: none"> • MCG care guidelines • ACOG recommendations • AAP recommendations • US Preventative Task Force • Evidence-based recommendations • CMS national and local coverage determinations • Apollo Managed Care guidelines • NIA Magellan recommendations • Peer-reviewed medical literature • ASAM criteria for SUD services
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Factor 3 Not Primarily for Convenience	
Definition	The requested service cannot be determined to be primarily convenient for the patient, the physician or other provider as opposed to the most cost-effective service for the best outcome based upon the patient’s condition and medical history.
Evidentiary Standards	<ul style="list-style-type: none"> • Medical history of patients • Claims reports • Patient history review • MCG care guidelines • ACOG recommendations • AAP recommendations • US Preventative Task Force • Evidence-based recommendations • CMS national and local coverage determinations • Apollo Managed Care guidelines • NIA Magellan recommendations • Peer-reviewed medical literature • ASAM criteria for SUD services

Prior Authorization

Description

Prior assessment that proposed services are medically necessary, an appropriate treatment for a particular patient and will be covered by the plan. Prior authorization may be referred to as prior authorization, prospective review, prior approval, precertification or preadmission approval.

Strategy

Prior authorization is a component of CareFirst’s utilization management program. It ensures that members receive appropriate care that is specific to their needs and consistent with evidence-based clinical criteria.

Process



In-network providers must obtain prior authorization for services with a prior authorization requirement. Requests for prior authorization may be submitted by fax, online portal, mail or phone. When a member receives (non-emergency) out-of-network care, the member is responsible for assuring that the provider requests prior authorization for services which require prior authorization.

Prior authorization is performed by applying plan terms and evidence-based clinical criteria. Coverage determination is rendered by qualified staff (RN, LCSW, LCW-C, LCPC). Only Medical Directors (MD, PhD) may issue a denial for medical necessity. Providers and members are notified of adverse benefit determinations consistent with state, federal and NCQA requirements. Applicable appeal rights are provided.

Applicable Benefit Classifications: inpatient in-network, inpatient out-of-network, outpatient in-network and outpatient out-of-network.

Refer to your plan documents and/or contracts to determine what services this NQTL is applied to. A standard list of CareFirst services subject to utilization management can be found [here](#).

Concurrent Review

Description

Concurrent review is a component of CareFirst's utilization management program for inpatient services. Concurrent review helps to ensure that members who are experiencing an inpatient hospitalization are receiving appropriate care based on their unique clinical needs. The process includes the application of evidence-based clinical guidelines, which encourage optimum clinical outcomes.

Strategy

For planned admissions, concurrent review begins when the initial authorization is ending and additional inpatient days are needed. For unplanned emergent admissions, concurrent review begins at first notification when prior authorization was not possible and the member is already hospitalized. Outpatient services do not use a concurrent workflow.

Process

Appropriate clinical staff will review the admission or concurrent inpatient hospitalization using evidence-based clinical guidelines. Coverage determination is rendered by qualified staff (RN, LCSW, LCW-C, LCPC). Only Medical Directors (MD, PhD) may issue a denial for medical necessity. Providers and members are notified of adverse benefit determinations consistent with state, federal and NCQA requirements. Applicable appeal rights are provided.

Applicable Benefit Classifications: inpatient in-network and inpatient out-of-network.

Refer to your plan documents and/or contracts to determine what services this NQTL is applied to.



Retrospective Review

Description

Retrospective review is a component of CareFirst's utilization management program. It is used to authorize services after they have been rendered. Retrospective review is only used to authorize services that require prior approval and approval was not obtained prior to service. Retrospective review is not applied to other situations. Retrospective review is not utilized to deny previously approved services.

Strategy

Retrospective review begins when CareFirst receives a notification or claim post-discharge that an inpatient hospitalization occurred, or post-service that outpatient services were rendered and prior authorization of the services was not previously obtained when required.

Process

Appropriate clinical staff will review the admission or concurrent inpatient hospitalization using evidence-based clinical guidelines. Appropriate clinical staff will review the admission or inpatient hospitalization using evidence-based clinical guidelines. Coverage determination is rendered by qualified staff (RN, LCSW, LCW-C, LCPC). Only Medical Directors (MD, PhD) may issue a denial for medical necessity. Providers and members are notified of adverse benefit determinations consistent with state, federal and NCQA requirements. Applicable appeal rights are provided.

Applicable Benefit Classifications: inpatient in-network and inpatient out-of-network.

Utilization Management (UM) Team and Process:

CareFirst has a standard operating procedure for the prior authorization reviews that applies to both MH/SUD services and M/S services. The written criteria and procedures are to ensure fair and consistent prior authorization reviews and utilization decisions.

CareFirst recognizes a responsibility to demonstrate a commitment of superior clinical quality service that is member centric, high touch, clinically appropriate, cost effective, data driven and culturally competent. This is achieved through an organization-wide, systematic and coordinated approach that involves input from and coordination with both internal and external stakeholders. These stakeholders include members, providers, state entities, CMS, business units and department and staff members. The UM program is designed to monitor, evaluate and manage the cost and quality of healthcare services delivered to our members. The program will ensure that services are medically necessary, are of high quality and are delivered at the appropriate level of care/place of service. This is inclusive of both physical and mental health services provided in an inpatient or outpatient setting.

Written UM policies and procedures define CareFirst's prior approval and utilization review program. All services authorized by the UM staff are evaluated against appropriate benefit packages and nationally accepted medical necessity criteria. The criteria are reviewed, revised and approved at least annually by the Quality Executive Committee (QEC). A designated senior practitioner, specifically the Chief Medical Officer (CMO), has significant involvement in the implementation of the



UM Program and related policies and procedures. A formal UM Committee, under the direction of the CMO, oversees the Utilization Review process.

Prior authorization decisions and processes are supervised by qualified licensed professionals. A licensed professional who has appropriate clinical experience in treating the enrollee's condition or disease makes a request for the CMO or Medical Director to review a request for service that does not meet medical necessity criteria. The CMO or Medical Director makes the final coverage determination if the clinician is unable to approve the request. A change in the amount, duration or scope that is less than requested must be made by a healthcare physician. Licensed physician consultants from Medical Review Institute of America (MRIA) are utilized to review cases from the appropriate specialty areas as needed.

A licensed physician oversees UM decisions to ensure consistent medical necessity decision making. Licensed doctoral-level clinical psychologists oversee behavioral health care UM decisions for psychological testing.

Licensed nurses or Licensed Clinical Social Workers (RN, LPN, LCSW) may approve benefit or medical necessity cases. These practitioners may not deny medical necessity cases.

Utilization Management Staff and their Responsibilities:

CareFirst Title	Qualifications
Medical Director/Chief Medical Officer	Board-certified Medical Doctor responsible for the development and implementation of UM processes, criteria and program outcomes. Oversees the operations of the UM department and is a liaison to the medical community regarding UM program operations. Clinical consultant for UM decisions: approves and denies care according to medical criteria and policies and procedures. Reports to the Chief Executive Officer (CEO) and supervises all other Medical Directors (e.g., Behavioral Health Medical Director, etc.). Chairs the UM Committee and the Pharmacy and Therapeutics (P&T) Committee.
CareFirst Medical Director, Behavioral Health	Board-certified Medical Doctor of Psychiatry who reviews and makes determinations based on medical necessity on behavioral health UM cases using evidence-based UM criteria and policies and procedures. Liaison to the behavioral health practitioner and provider communities. Provides information and expertise to the UM behavioral health staff. Reports to the Medical Director, is an enrollee of the UM Committee and is a consultant to the P&T Committee.
CareFirst Medical Director, Behavioral Health	Medical degree from an accredited medical school, completion of an American residency program, minimum of five years clinical practice experience in the field of Psychiatry, and two years managed care experience with accreditation experience. Board Certification includes American Board of Psychiatry and Neurology.



CareFirst Title	Qualifications
Director of Utilization Management	An RN who is responsible for intake, precertification, concurrent review and retrospective review activities of the department. Develops and maintains policies and procedures for assigned areas. Approves requested care per UM criteria and policies and procedures. May deny care based on benefits or contract issues. Supervises all RN, LPN staff and UM coordinators, and is responsible for department operations. Reports to the Clinical Director of Government Programs with a dotted line to the Chief Medical Officer.
Utilization Management Manager/Supervisor	Assists UM director with day-to-day operations, oversees completion of reviews by UR reviewers, problem-solves, conducts audits and prepares documents for weekly UM Meetings. Reports to the Director of UM.
Utilization Management Reviewer	A Licensed Nurse who conducts UM review activities. Monitors and coordinates care with participating practitioners, enrollees and provider organizations using established criteria. Collects data for the precertification, concurrent review and retrospective review processes. Approves requested care per UM criteria and policies and procedures. May deny authorization requests based on administrative criteria (i.e., benefit or contractual limitations). In the event that medical necessity is not met, the reviewer would submit the authorization request to a MD for the medical necessity determination.
Vice President of Pharmacy and Therapeutics	The Doctor of Pharmacy is responsible for developing and maintaining the formulary and formulary policies and procedures. Researches, approves and denies requests for drugs consistent with formulary policies and procedures and UM criteria. Reports to the Medical Director/CMO and is a member of the P&T Committee. Provides support to the P&T Committee and manages the MCO's relationship with the Pharmacy Benefits Manager (PBM).
Physician Advisors	Board-certified medical doctors who are available for review of UM cases (including appeals) or in the case of an appeal. They will research and either approve or deny the authorization request according to UM criteria and policies and procedures.

Utilization tracking and trending data are reviewed by the UM Committee quarterly and submitted quarterly to the QEC. The data are analyzed by the QEC to determine outcomes related to overutilization or underutilization of services.

Prior Authorization, Concurrent Review and Retrospective Review

Factor 1	Medically Necessary
Definition	The service must be medically necessary. Refer to the medical



	necessity NQTL above for more information.
Evidentiary Standards	Refer to the medical necessity NQTL above for more information.

Factor 2	Length of Stay
Definition	The proposed length of stay should be similar to other stays with the same or similar diagnosis in the same or similar place of service. High levels of variations in length of stay that show patients stayed longer than the average stay or stays over 30 days may for the same or similar diagnosis may impact the determination of this factor.
Evidentiary Standards	<ul style="list-style-type: none"> • MCG guidelines • ASAM guidelines

Factor 3	Standards of Care
Definition	To determine if the quality standards for the proposed treatment or service will be met or whether further research may need to be done to validate. Deviations from generally accepted national quality standards for a specific diagnosis or disease category may also impact this factor's determination.
Evidentiary Standards	<ul style="list-style-type: none"> • MCG guidelines • ASAM guidelines

Factors 4 and 5	Clinical Efficacy and Appropriateness
Definition	The clinical efficacy and appropriateness of a proposed treatment or service. Clinical efficacy refers to achieving a desired treatment effect. The proposed treatment or service must be safe and effective for the diagnosis based upon the information provided about the patient's condition and the proposed treatment or service will provide the optimal clinical outcome for the diagnosis based upon the information provided about the patient's condition.
Evidentiary Standards	<ul style="list-style-type: none"> • MCG guidelines • ASAM guidelines • Peer-reviewed medical literature • Claims analysis • Patient records and health history



Network NQTLs

Network Adequacy

Description

CareFirst assesses network adequacy based on access standards that are consistent with State requirements, industry standards (NCQA) and Centers for Medicare and Medicaid Services (CMS).

Strategy

When identifying areas that require provider recruitment efforts, CareFirst utilizes geographic data and network adequacy reporting. Network adequacy reporting is created at least annually and more frequently as needed to address any adequacy concerns. The Quality Improvement Council (QIC) is the committee with oversight of network adequacy, network access and availability.

CareFirst will attempt all contracting efforts possible to close identified supply gaps. The Strategic Contracting Committee has oversight of these efforts. When there is a supply gap, members may seek an exception to obtain out-of-network care at an in-network benefit level. CareFirst also evaluates out-of-network utilization reporting and member complaints to identify areas of network need.

During plan implementations, network disruption reports are generated to identify possible supply gaps generated by adding membership and proactive contracting steps are taken in response, as needed. The CareFirst sales or service teams may submit a customer-specific request for provider contracting. If review of the network determines there is a network need, contracting will pursue a contract with the provider as appropriate.

Applicable Benefit Classifications: inpatient in-network, outpatient in-network and emergency care.

Factor 1		State Standards
Definition		When states have a mandated, numeric, applicable measure.
Evidentiary Standards		State regulatory requirements

Factor 2		Industry Standards
Definition		CareFirst follows industry standards and expectations as identified by industry leaders.
Evidentiary Standards		<ul style="list-style-type: none">• NCQA network standards• CMS/Medicare network adequacy guidance

Factor 3		Contractual Plan Requirements
Definition		Additional network adequacy requirements agreed upon between CareFirst and the plan. These requirements would be in addition to any other state and federal requirements.



Evidentiary Standards	Plan contracts
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Factor 4	Network Need
Definition	Network monitoring and testing to determine and address network gaps/needs.
Evidentiary Standards	<ul style="list-style-type: none"> • Out-of-network utilization trends • Customer access complaints • Network disruption studies • Claim data and trends

Credentialing

Description

Credentialing is used to ensure providers meet and continue to maintain the qualifications and standards needed to furnish services to members within the network or practice area.

Strategy

CareFirst uses defined credentialing and recredentialing policies, NCQA standards and applicable state or federal requirements to validate provider qualifications and determine if providers may join the network or remain in the network.

Process

For new providers, the process begins with the provider/facility application. Providers submit a CAQH profile, facility-based application or state application, as applicable. CareFirst will validate education, licensing, experience and other requirements. Validation is consistent with NCQA standards and applicable state and federal requirements. When the Medical Director determines that an application is complete and meets credentialing requirements, it is referred to the Credentialing Advisory Committee (CAC) for approval. An application that does not meet credentialing requirements may be denied. If an application is denied, appeal rights are provided. Continued monitoring of network providers occurs to identify issues with licensing or sanctions. Recredentialing occurs every three years.

Credentialing Committee

CareFirst maintains a peer-review committee, the Credentialing Committee (CC), comprised of network providers who bring technical knowledge of current medical practice within the communities served. The CC includes local providers practicing in multiple specialties including behavioral health. The CC is chaired by the CareFirst Medical Director. The Medical Director is responsible for the credentialing program. The Chief Medical Officer also sits on the CC. The CC meets monthly and more often on an ad-hoc basis.

Membership of the CC includes representation from a range of participating practitioners in CareFirst's network, including representation from:



- Pediatric primary care (minimum of one pediatrician)
- Adult primary care (minimum of one family practice or internist)
- Medical and/or surgical specialists
- Female adolescent or adult specialist (such as an OB/BYN); and
- Behavioral health

The CC has the authority to make the following decisions:

- Approve
- Deny
- Pend for further information

The CC develops and implements the credentialing/recredentialing processes to select and evaluate practitioners based on their ability to deliver care through recommendations for credentialing decisions using a peer review process.

The Committee has the following responsibilities:

- On a weekly basis, reviews a list of names of all the practitioners who meet CareFirst's established credentialing criteria for initial or continued participation in the CareFirst practitioner networks.
- Reviews summary information (the complete credentialing file is available for review if requested) for practitioners who do not meet CareFirst's established credentialing criteria for initial or continued participation in the CareFirst practitioner networks.
- Recommends actions to the CareFirst Medical Director regarding applicants (defer for additional information, approve or deny participation, approve or deny continued participation in provider programs).
- Reviews and advises the CareFirst Medical Director concerning issues and/or appeals of initial credentialing and recredentialing decisions.
- Annually reviews and discusses credentialing policies, procedures and standards, and recommends revisions as necessary.
- Reviews providers that are no longer in good standing.
- Reviews and approves entities recommended for delegated credentialing arrangements.
- Reviews delegated credentialing reports and develops recommendations for improvements.
- Meets routinely throughout the year to ensure timely credentialing decisions, maintains contemporaneous minutes, documenting discussions about credentialing, and reporting credentialing activities and recommendations.

Role of the Medical Director:

The Medical Director is responsible for the clinical aspects of the credentialing program. The Medical Director reviews and approves all credentialing and recredentialing applicants for clinical history including licensure sanctions and malpractice determinations. This also includes reviewing appeals of credentialing decisions. The Medical Director (or designee) chairs the credentialing committee.

Credentialing Timelines:

Within 30 days of receipt of a completed application, providers are notified of intent to continue or



reject the application for network participation. Providers are initially credentialed within 120 days from the notification of a complete application and are recredentialed on a 36-month cycle.

Initial and Re-Credentialing Requirements, Sources and Criteria:

To complete the credentialing process, the credentialing file for each practitioner must include the applicable data elements to satisfy all the required factors. The receipt of an application from a provider triggers the credentialing process. If the application is not complete, CareFirst will inform the provider in writing to allow for corrections and/or to provide additional information. The completed file is then forwarded to Medical Direct and the CC for review and approval and a final decision is made.

Providers requesting initial participation will be notified of the decision within 150 days of receipt of a completed application or within 10 days of the CC decision, whichever is earlier. This notification may occur electronically or via standard mail. For denial decisions, letters are sent that include instructions for the provider on how to appeal the decision.

The re-credentialing process incorporates reverification and the identification of changes in the provider's licensure, sanctions, certification, health status and/or performance information (including, but not limited to, malpractice experience, hospital privilege or other actions) that may reflect on the provider's professional conduct and competence. This information is reviewed to assess if the provider continues to meet CareFirst credentialing standards. All applicable providers in the network within the scope of credentialing are required to be recredentialed every 36 months.

As for the credentialing of institutional providers, the RFI must be completed and attested to by the provider within 180 days from submission to CareFirst. Credentialing documents must meet the standards as defined on the CareFirst Credentialing Requirements for Assessment and Reassessment of Organizational Providers Chart or as defined by the CAC.

Requirements for Professional Providers

- Valid, current, unrestricted licensure
- Prescribers only (MD, NP): Valid, current, Drug Enforcement Agency and Controlled Dangerous Substance registration, and as applicable, for each state where the practitioner practices
- Appropriate education and training in a relevant field
- Board certification, if applicable
- Review of work history
- M/S MDs only: Active, unrestricted, admitting privileges at a participating network hospital, except as otherwise agreed to by CareFirst in its sole discretion
- At least 20 office hours per week to see patients
- Acceptable history of professional liability claims
- Acceptable history of previous or current state sanctions, Medicare/Medicaid sanctions, restrictions on licensure, hospital privileges and/or limitations on scope of practice
- Attestation to ability to perform the essential functions of a clinical practitioner and lack of present illegal drug use
- Current malpractice insurance coverage with minimum limits

Requirements for Institutional Providers/Facilities

- A completed Request for Information (RFI) Application and a Facility Data Sheet for each location along with all required credentialing documents for professional providers



- Institutional and ancillary providers are required to have a physical location in the CareFirst service area and meet all credentialing requirements
- Institutions requesting to participate in CareFirst’s provider network need to have both State Licensure and CMS certification

Applicable Benefit Classifications: inpatient in-network, outpatient in-network and emergency care.

Factor 1		Completed Application and Attestation
Definition	The provider/facility submits a completed application and attestation to the ability to perform the essential functions of a clinical practitioner and lack of present illegal drug use. CareFirst validation and ongoing monitoring of information provided within the application. (Recredentialing every 3 years)	
Evidentiary Standards	<ul style="list-style-type: none"> • Receipt and review of documents for accuracy • CareFirst provider manual • NCQA standards • State or federal requirements • CAQH application, facility application or state application, as applicable • CareFirst questionnaire • Attestation • Required documentation • OIG • State licensing boards 	

Factor 2		Licensure
Definition	The provider has a valid, current, unrestricted licensure and a valid, current, Drug Enforcement Agency (DEA) and Controlled Dangerous Substance (CDS) registration, and as applicable, for each state where the practitioner practices.	
Evidentiary Standards	<ul style="list-style-type: none"> • State law licensing requirements • Federal law licensing requirements • DEA registration • CDS registration 	

Factor 3		Education and Training
Definition	The provider has appropriate education and training.	
Evidentiary Standards	<ul style="list-style-type: none"> • State law licensing requirements (as applicable) 	

Factor 4		Board Certification
Definition	The provider has appropriate board certification (as applicable).	
Evidentiary Standards	<ul style="list-style-type: none"> • Board certification records • State law licensing requirements (as applicable) 	



Factor 5		Liability Claims
Definition	Acceptable history of professional liability claims. The threshold is if the applicant's malpractice history has any cases that settled with totals exceeding \$3,000,000 in the past 10 years or has any case resulting in death within the past 10 years. For recredentialing, the provider cannot have more than 5 complaints in the prior credentialing cycle.	
Evidentiary Standards	<ul style="list-style-type: none"> • NCQA guidelines • Liability claims review 	

Factor 6		Appropriate Malpractice Insurance
Definition	Current malpractice insurance coverage with minimum limits.	
Evidentiary Standards	<ul style="list-style-type: none"> • NCQA guidelines and standards • Provider insurance review 	

Factor 7		Accreditation
Definition	Appropriate accreditation from appropriate accrediting bodies (as applicable).	
Evidentiary Standards	<ul style="list-style-type: none"> • State law licensing requirements • Federal law licensing requirements 	

Facility and Provider Reimbursement

Description

CareFirst uses the following methodologies to establish reimbursement for providers and facilities.

Strategy

Facility:

M/S and MH/SUD facilities are reimbursed at 100% of agreed upon contracted rates and fee schedules. Facilities under the purview of a state reimbursement model would be reimbursed according to the state reimbursement model. A contract offer would be developed using the factors below. If the contract offered is not accepted, the additional factors provided may be used in negotiation.

Using the factors below, CareFirst maintains provider reimbursement consistent with industry benchmarks and within market value for the providers' geographic location for the service provided. It is CareFirst practice to reimburse out-of-network provider professional and at 100% of the In-network rate or fee schedule for M/S and MH/SUD. Rates are established in the same manner as in-network, using geographic region, provider location, market data and industry benchmarks.



Provider:

Using the factors below, CareFirst maintains provider reimbursement consistent with industry benchmarks and within market value for the providers' geographic location for the service provided.

CareFirst develops and maintains a standard fee schedule for use with M/S and MH/SUD providers. The fee schedule is reviewed annually and updated through ongoing evaluation and maintenance (e.g., AMA code additions/deletions) with adjustments/modifications typically once a year. Fee schedules are updated periodically in response to market research and/or in response to industry benchmark changes, such as changing CMS rates.

CareFirst's methodology includes CMS rates as the primary source. CMS RVUs incorporate the provider's location, specialty, license type, board certification, education, relevant training and services. Reimbursement analysis includes ensuring that the % of CMS reimbursement for M/S does not exceed the % of CMS reimbursement for MH/SUD. This analysis is performed by a CareFirst Reimbursement Analyst and confirmed by the Manager of Provider Reimbursement.

Additionally, external market rates are used to ensure that CareFirst rates are consistent with reimbursement in the provider's geographic location. When changes occur, CareFirst will notify the impacted providers in accordance with contractual agreements.

If a M/S or MH/SUD provider does not accept the standard fee schedule, additional factors may be considered in negotiating contract terms upward. CareFirst's network demand for the given specialty/services may be considered, and/or the size of the provider group and the number of members served may need to be considered. In negotiations, most often the provider can share a desired fee schedule arrangement, based on competitive rates offered to them. Competitive market data would be considered by CareFirst.

Facility Reimbursement—In-Network Facilities

Applicable Benefit Classifications: inpatient in-network, outpatient in-network and emergency care.

Factor 1	State Reimbursement
Definition	State established reimbursement, if applicable.
Evidentiary Standards	<ul style="list-style-type: none">State law and associated reimbursement rates

Factor 2	Facility Type
Definition	Type of facility i.e. inpatient acute, inpatient non-acute or outpatient facility-type.
Evidentiary Standards	<ul style="list-style-type: none">Industry standards according to facility type

Factor 3	Service Type
Definition	The type of services provided.
Evidentiary Standards	<ul style="list-style-type: none">Most current version of code sets

Factor 4	Relative Value Units (RVUs)
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Definition	<p>CMS RVUs: $(\text{Work RVU} \times \text{work GPCI}) + (\text{PE RVU} \times \text{PE GPCI}) + (\text{MP RVU} \times \text{MP GPCI}) \times \text{CF} = \text{CMS benchmark rate}$</p> <p>The work RVU = relative time and intensity associated with furnishing services. The Practice Expense (PE) RVU = the costs of maintaining a practice. The Malpractice (MP) RVU = the costs of malpractice insurance. Geographic Practice Cost Indices (GPCIs) = geographic variations in the costs of practicing medicine in different areas of the country. Conversion Factor (CF) = the sum of the geographically adjusted RVUs by a CF in dollars.</p>
Evidentiary Standards	<ul style="list-style-type: none"> • CMS RVUs • CMS per diem rates

Factor 5 Market Rates and Geographic Location	
Definition	Applicable market rates for the services based on geographic region as defined by CMS.
Evidentiary Standards	<ul style="list-style-type: none"> • Facility application • External market rates i.e., Truven Health Analytics • CMS rates as defined by Medicare geographic region

Additional Factors for Negotiation—In-Network Facilities

Applicable Benefit Classifications: inpatient in-network, outpatient in-network and emergency care.

Factor 1 Network Need	
Definition	An identified network gap identifies a need to negotiate more aggressively for the given specialty or expertise.
Evidentiary Standards	<ul style="list-style-type: none"> • Geo-access reporting • OON utilization • Member complaints specific to network adequacy

Factor 2 Patient Volume/Facility Size	
Definition	Patient volume or size of the facility may need to be considered.
Evidentiary Standards	<ul style="list-style-type: none"> • Claims data • Provider directory • Facility application

Additional Factors for Re-Negotiation—In-Network Facilities



Applicable Benefit Classifications: inpatient in-network, outpatient in-network and emergency care.

Factor 1	Special Investigations Unit (SIU) Activity—Fraud, Waste, Abuse
Definition	If a provider has a case or history with SIU (i.e. fraud or abuse) is considered before engaging in negotiations.
Evidentiary Standards	<ul style="list-style-type: none"> CareFirst SIU data

Factor 2	Facility Quality Outcomes
Definition	The quality outcomes of facilities.
Evidentiary Standards	<ul style="list-style-type: none"> CareFirst quality data Provider scorecards

Out-of-Network Facilities—Emergency Services

Applicable Benefit Classifications: emergency care.

Factor 1	State Reimbursement Requirements
Definition	The state established reimbursement, if applicable.
Evidentiary Standards	<ul style="list-style-type: none"> State law and associated reimbursement rates

Factor 2	Qualified Payment Amount (QPA)
Definition	The qualified payment amount per Consolidated Appropriations Act where state model does not apply).
Evidentiary Standards	<ul style="list-style-type: none"> CAA requirements In-network rate

Provider Reimbursement

Applicable Benefit Classifications: inpatient in-network, inpatient out-of-network, outpatient in-network, outpatient out-of-network and emergency care.

Factor 1	Provider Type, Expertise and Licensure
Definition	Assessment of provider specialty, license type (MD or non-MD), training, education, board certification and experience.
Evidentiary Standards	<ul style="list-style-type: none"> ICMS guidelines Industry benchmarking data Provider application Medicare reductions for limited licensed provider

Factor 2	Medicare Rates
Definition	Reimbursement is based on Medicare reimbursement rates.



	<p>Behavioral health services: Should be no less than Medicare when possible. At a minimum the percentage of Medicare used for these services should be no less than the methodology used for E/M office visits codes (99202-99215).</p> <p>The work RVU = relative time and intensity associated with furnishing services.</p> <p>The Practice Expense (PE) RVU = the costs of maintaining a practice.</p> <p>The Malpractice (MP) RVU = the costs of malpractice insurance.</p> <p>Geographic Practice Cost Indices (GPCIs) = geographic variations in the costs of practicing medicine in different areas of the country.</p> <p>Conversion Factor (CF) = the sum of the geographically adjusted RVUs by a CF in dollars.</p>
Evidentiary Standards	<ul style="list-style-type: none"> • Rates paid by Medicare under the MPFS or MAC for local jurisdictions • CMS fee schedule and annual changes

Factor 3	Service Type
Definition	The type of services provided.
Evidentiary Standards	<ul style="list-style-type: none"> • Most current version of code sets

Factor 4	Market Rates and Geographic Location
Definition	Applicable market rates for the services based on geographic region as defined by CMS.
Evidentiary Standards	<ul style="list-style-type: none"> • Provider application • External market rates i.e., Truven Health Analytics • CMS rates as defined by Medicare geographic region

Factor 5	Market Demands and Specialized Services
Definition	Relies on the provider landscape and member needs, could be impacted by geography, abundance or lack of providers ability to handle specialized services or member need and access.
Evidentiary Standards	<ul style="list-style-type: none"> • Provider feedback • Competitive intelligence • Provider correspondence that may include blinded competitor information, this information is generally submitted by providers when providing market validation or evidence that other payors are allowing higher rates



	<ul style="list-style-type: none"> Industry benchmarking data such as purchased market benchmarking data, i.e., IDB Watson and Truven
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Additional Factors for Negotiation—In-Network Providers

Applicable Benefit Classifications: inpatient in-network, outpatient in-network and emergency care.

Factor 1	Network Need
Definition	An identified network gap identifies a need to negotiate more aggressively for the given specialty or expertise.
Evidentiary Standards	<ul style="list-style-type: none"> Geo access reporting OON utilization Member complaints specific to network adequacy

Factor 2	Patient Volume and Size
Definition	The patient volume may need to be considered for higher-volume providers. Additionally, the size of the practice (number of providers in the group) may need to be considered.
Evidentiary Standards	<ul style="list-style-type: none"> Claims data Provider directory Provider application and affiliations

Factor 3	Competitive Intelligence
Definition	Information about industry reimbursement rates or evidence of cost of care provided.
Evidentiary Standards	<ul style="list-style-type: none"> Industry benchmarking data Provider complaints and correspondence Competitive research Rate review Cost of care review

Additional Factors for Re-Negotiation—In-Network Providers

Applicable Benefit Classifications: inpatient in-network, outpatient in-network and emergency care.

Factor 1	Special Investigations Unit (SIU) Activity—Fraud, Waste, Abuse
Definition	If a provider has a case or history with SIU (i.e. fraud or abuse) is considered before engaging in negotiations.
Evidentiary Standards	<ul style="list-style-type: none"> CareFirst SIU data



Factor 2	Quality Outcomes
Definition	The quality outcomes of providers.
Evidentiary Standards	<ul style="list-style-type: none">• CareFirst quality data• Provider scorecards



Pharmacy NQTLs

Medical Necessity of Prescription Drugs

Description

Medical Necessity means healthcare services or supplies that a healthcare provider, exercising prudent clinical judgment, renders to or recommends for a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms.

These healthcare services or supplies are:

- in accordance with generally accepted standards of medical practice,
- clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for a patient's illness, injury or disease;
- not primarily for the convenience of a patient or healthcare provider,
- and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results in the diagnosis or treatment of that patient's illness, injury or disease.

Strategy

In reviewing medical necessity as it applies to M/S or MH/SUD medication, CVS uses national clinical guidelines, FDA approved labeling, published peer-reviewed literature, a nationally recognized drug compendia, accepted clinical practice guidelines, consensus statements and standards of care as defined by clinical literature.

Process

CVS Caremark (CVSC) utilizes the Clinical Program Oversight process for review and approval of any new criteria, updates, and annual review of utilization criteria and clinical program content. As part of this process, the prior authorization criteria and clinical program will be reviewed by one or more External Consultants, who are practicing in the relevant clinical area. The CVS Caremark National P&T Committee is an external advisory body of expert members from a variety of medical specialties, who reviews and approves all UM criteria (i.e., prior authorization, step therapy and quantity limits outside of FDA-approved labeling). CVS Caremark develops standard prior authorization programs and a health plan or client chooses which prior authorization programs to include in the plan offering.

Applicable Benefit Classifications: prescription drugs.

Factor 1	Clinical Appropriateness
Definition	The prescription drug must be clinically appropriate and considered effective for the patient's illness, injury or disease. The service must be clinically appropriate and effective per the accepted guidelines based upon the patient's condition.
Evidentiary Standards	<ul style="list-style-type: none">• FDA labeling• FDA approval



	<ul style="list-style-type: none"> • Peer-reviewed clinical literature <ul style="list-style-type: none"> ○ E.g.: American Psychiatric Association, American Academy of Neurology • Approved drug compendia • Clinical practice guidelines, consensus statements or comparable publications <ul style="list-style-type: none"> ○ E.g.: Cochrane Database • Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references • Appropriate clinical drug information from other sources as applicable <ul style="list-style-type: none"> ○ Package inserts
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Factor 2 Clinical Effectiveness	
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Definition	The drug must be effective clinically as determined by accepted guidelines and proper professional and governing bodies.
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Evidentiary Standards	<ul style="list-style-type: none"> • FDA labeling • FDA approval • Peer-reviewed clinical literature <ul style="list-style-type: none"> ○ E.g.: American Psychiatric Association, American Academy of Neurology • Approved drug compendia • Clinical practice guidelines, consensus statements, or comparable publications <ul style="list-style-type: none"> ○ E.g.: Cochrane Database • Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references • Appropriate clinical drug information from other sources as applicable <ul style="list-style-type: none"> ○ Package inserts
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Factor 3 Safety of Treatment	
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Definition	The drug must be determined as 'safe' by accepted guidelines and proper professional and governing bodies.
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Evidentiary Standards	<ul style="list-style-type: none"> • FDA labeling • FDA approval • Peer-reviewed clinical literature <ul style="list-style-type: none"> ○ E.g.: American Psychiatric Association, American Academy of Neurology • Approved drug compendia • Clinical practice guidelines, consensus statements, or comparable publications <ul style="list-style-type: none"> ○ E.g.: Cochrane Database, • Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
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	<ul style="list-style-type: none"> • Appropriate clinical drug information from other sources as applicable <ul style="list-style-type: none"> ○ Package inserts
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Prior Authorization of Prescription Drugs

Description

Prior authorization is a utilization management tool used to determine whether the intended use of a prescription drug meets a plan’s medical necessity standards. Prior authorization is granted when a member meets the plan’s medical requirements.

Strategy

Prior Authorization is required before members fill prescriptions for certain drugs. The doctor may need to provide medical history or laboratory tests to determine if these medications are appropriate. When prior authorization is required, medications will not be covered by the plan if prior authorization is not obtained. Pharmacy prior authorization is typically utilized in drug classes where the potential for use for unapproved indications exists, the potential for inappropriate over- or under-utilization exists, or when safety concerns exist with a drug or drug class. Members or providers may refer to the prescription formulary list, to identify which medications require prior authorization.

Process

Prior authorization is required for some medications to be covered by the Plan. Requests for prior authorization may be submitted by fax, online portal, mail, or phone. Prior authorization is performed by applying evidence-based clinical criteria. A coverage determination is rendered by licensed pharmacists in good standing and physicians who are board-certified or eligible in the same specialty as the treatment under review. In accordance with Maryland law, any denials of coverage involving mental health and substance use disorder drugs are rendered by physicians who are actively practicing or have expertise in substance use or mental health disorders or are board-certified or eligible in the treatment of substance use or mental health disorders.

CVS Caremark utilizes the Clinical Program Oversight process for review and approval of any new criteria, updates, and annual review of utilization criteria and clinical program content. As part of this process, the prior authorization criteria and clinical program will be reviewed by one or more External Consultants, who are practicing in the relevant clinical area. The CVS Caremark National P&T Committee (P&T Committee) is an external advisory body of expert members from a variety of medical specialties, who reviews and approves all UM criteria (i.e., prior authorization, step therapy and quantity limits outside of FDA-approved labeling). CVS Caremark develops standard prior authorization programs and chooses which prior authorization programs to include in the plan offering.

Applicable Benefit Classifications: prescription drugs.

Refer to your plan documents and/or contracts to determine what prescription drugs this NQTL is applied to.

Factor 1	Medically Necessary
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Definition	The prescription drug must be medically necessary. Refer to the medical necessity of prescription drugs NQTL above for more information.
Evidentiary Standards	Refer to the medical necessity of prescription drugs NQTL above for more information.

Factor 2 Appropriateness—Safety	
Definition	Patient safety concerns with a drug or drug class; unknown long-term safety or durability.
Evidentiary Standards	<ul style="list-style-type: none"> • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM) • Accepted clinical practice guidelines, consensus statements or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care for M/S drugs • Accepted clinical practice guidelines, consensus statements or comparable publications – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD for MH/SUD drugs. • Comparison of similar drugs in terms of safety and efficacy • Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

Factor 3 Appropriateness—Test Results	
Definition	The applicable lab values or other test results required for appropriate treatment.
Evidentiary Standards	<ul style="list-style-type: none"> • Accepted clinical practice guidelines, consensus statements or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care for M/S drugs • Accepted clinical practice guidelines, consensus statements or comparable publications – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD for MH/SUD drugs

Factor 4 Appropriateness—Use of Medication	
Definition	The appropriate medication uses for indications or conditions based on national guidelines.



Evidentiary Standards	<ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug, Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex
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Factor 5	Appropriateness—Population Use
Definition	The drug is used in appropriate patient populations. Use limited to a specific population based on FDA-approved indications, standard clinical practice and guidelines
Evidentiary Standards	<ul style="list-style-type: none"> • Accepted clinical practice guidelines, consensus statements or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care for M/S drugs • Accepted clinical practice guidelines, consensus statements or comparable publications – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD for MH/SUD drugs • FDA product labeling for approved uses and safety information • Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references

Factor 6	Appropriateness—Potential for Misuse
Definition	The potential for inappropriate or off-label use.
Evidentiary Standards	<ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information

Factor 7	Optimal Patient Outcomes
Definition	Opportunity for optimizing patient outcomes, to ensure treatment goals of the drug are being met.
Evidentiary Standards	<ul style="list-style-type: none"> • Comparison of similar drugs in terms of safety and efficacy • Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department • Review of any new criteria, updates and annual review of utilization management criteria and clinical program content by external clinical experts who are physicians practicing in the relevant clinical area • Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM)



Factor 8		Availability of Alternatives
Definition	Availability of a generic equivalent or alternative available on preferred tier.	
Evidentiary Standards	<ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug, Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex • Review of any new criteria, updates and annual review of utilization management criteria and clinical program content by external clinical experts who are physicians practicing in the relevant clinical area • Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM) 	

Factor 9		Availability of Other Dosage Forms
Definition	The availability of multiple other dosage forms availability on a preferred tier.	
Evidentiary Standards	<ul style="list-style-type: none"> • Accepted clinical practice guidelines, consensus statements or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care for M/S drugs • Accepted clinical practice guidelines, consensus statements or comparable publications – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD for MH/SUD drugs 	

Factor 10		Reduce Fraud, Waste, Abuse
Definition	Decisions to reduce waste, unnecessary drug use, fraud or abuse.	
Evidentiary Standards	<ul style="list-style-type: none"> • Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department • Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee 	

Factor 11		Additional Treatment Requirements
Definition	A requirement for additional treatment supportive therapies including behavioral counseling, diet therapy, case management and other standard non-drug supportive therapies.	



Evidentiary Standards

- Accepted clinical practice guidelines, consensus statements or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care for M/S drugs

Step Therapy of Prescription Drugs

Description

Step Therapy (ST) is a pharmacy UM strategy which encourages the use of equally effective and lower-cost medications before trying a higher-cost alternative. ST is generally used to promote the use of the most cost-effective products in the therapeutic class, provided efficacy and safety are equivalent, and the intended use of the drug meets the plan's medical necessity standards. Step therapy protocols require that alternative drugs be tried first, when clinically warranted and for a certain duration before the prescribed drug can be covered by a plan.

Strategy

Step therapy is typically employed in therapeutic classes with broad generic availability. ST promotes the use of the most cost-effective products in the therapeutic class, provided efficacy and safety are equivalent and the intended use of the drug meets the plan's medical necessity standards with the potential for savings via increased utilization of generics and/or lower-cost brands.

Process

The clinical pharmacists in the UM Development department use the factors, sources and evidentiary standards to understand the drug's place in therapy and apply the drug information to derive clinical content for step therapy criteria. This outcome is reviewed by internal clinical pharmacists, medical directors and external expert consultants.

