CareFirst Non-Quantitative Treatment Limits (NQTL) Disclosure Form

Mental Health Parity, as defined by the Mental Health Parity and Addiction Equity Act (MHPAEA), requires that treatment limitations are no more stringently applied to mental health and substance use benefits (MH/SUD), than they are applied to medical and surgical benefits (M/S).

Non-quantitative treatment limits (NQTLs) represent strategies, policies, and processes that limit the scope or duration of benefits, or how benefits are administered. Evaluation of NQTLs utilizes a 5-step process to include: descriptions, strategies, policies, and processes; as well as (step 1) factors, (step 2) evidentiary standards, and (step 3) sources. These steps conclude in a (step 4) written and (step 5) operational summary(s).

CareFirst has performed an analysis of mental health parity as required by state law and has submitted the report to the corresponding state agency. The following summary of that report is intended for members and providers as a part of the disclosure process; it does not constitute legal advice.

If you have questions on your specific health plan, please contact: Member Services at the phone number on the back of your member ID card. **If you have any questions on this summary, please contact:** CareFirst Mental Health Parity Office@CareFirstMentalHealthParity@carefirst.com

Medical Necessity

Description: Medical Necessity means health care services or supplies that a health care 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.

Consistent with industry standard for health insurance benefits, all benefits covered under this plan are required to be medically necessary to be covered services. Emergency services do not require prior authorization but must be Medically Necessary.

Factors:

The factors apply to Medical Services (M/S) and Mental Health/ Substance Abuse Disorders (MH/SUD):

1. Clinical Appropriateness
2. Clinical Effectiveness
3. Safety of Treatment

Evidentiary Standards:

The following evidentiary standards are used to evaluate the clinical appropriateness, effectiveness and safety of M/S and MH/SUD treatments and services. All evidentiary standards below apply to all factors:

1. Evidenced-based clinical criteria and guidelines
2. Peer reviewed literature
3. Clinical trials and studies
4. Professional opinion
5. Publications by professional societies or government agencies

Sources:

The following sources are used to define evidentiary standards. Please note that the sources are also evidentiary standards. (i.e.: Peer reviewed literature is also the evidentiary standard):

1. Evidenced-based clinical criteria and guidelines
2. Peer reviewed literature
3. Clinical trials and studies
4. Professional opinion
5. Publications by professional societies or government agencies

Written Summary:

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), and The American Society of Addiction Medicine (ASAM) criteria (for SUD).

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 MD or RN license in Maryland, Virginia, or the District of Columbia with a minimum of 7-10 years 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 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.

All CareFirst M/S and MH/SUD policies in the CareFirst Medical Policy Reference Manual are developed based on the most recent peer review literature and are reviewed by CareFirst's chief medical officer, senior medical directors, and the behavioral health medical director. The criteria are always used in conjunction with an assessment of the needs of the individual patient. All of CareFirst's medical and behavioral health policies are available on www.carefirst.com.www.carefirst.com.

CareFirst follows the same model of care and utilization management processes for both medical and behavioral health and substance use disorder services. Clinical criteria, clinical policy, and the qualification of clinical reviewers are identical for M/S and MH/SUD, (except for where a difference such as a MH/SUD Medical Director reviewing MH/SUD services), is warranted and appropriate. Accordingly, CareFirst has performed an analysis in writing and has determined that Medical Necessity is no more stringently applied to MH/SUD benefits, than it is to M/S benefits.

Operational Summary:

CareFirst conducts monthly Care Management audits to help ensure that medical necessity criteria are applied in a consistent and impartial manner. The Interrater Reliability Monitoring program is in place to evaluate the consistency with which Medical Directors, Physician Reviewers and Registered Nurses apply Medical, Behavioral Health and Substance Use, Pharmacy, and Dental medical necessity criteria in decision making.

Additionally, CareFirst monitors Care Management outcomes to ensure utilization management practices are not more stringently applied to MH/SUD benefits.

Prior Authorization Review Process

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 also be referred to as prospective review, prior approval, precertification, or preadmission approval. CareFirst may also require the member or the provider to get prior authorization for certain drugs. This means that approval from CareFirst is needed before certain prescriptions can be filled. If approval is not received, the drug may not be covered.)

Services which require prior authorization:

- Hospital Inpatient Services; including Ancillary services
- Inpatient Mental Health and Substance Use Disorder Services
- Residential treatment center services, except for emergency admissions
- Inpatient rehabilitation
- Outpatient rehabilitation therapy (physical therapy, speech therapy, occupational therapy, chiropractic, and acupuncture)
- Outpatient testing
- Outpatient surgery
- Facility based office visits
- Habilitative Services
- Organ and Tissue Transplants
- Controlled Clinical Trials
- Air Ambulance Services. (Except for Medically Necessary air ambulance. Services in an emergency).
- Skilled Nursing Facility
- Home Health Services
- Hospital Services
- Medical Devices and Supplies
- Imaging/Radiology
- Lab Testing
- Medications prescribed while in an inpatient or outpatient place of service
- Gender Reassignment Services

- Infusion Services
- Radiation Therapy
- Outpatient Chemotherapy
- Outpatient Dialysis
- Genetic Testing
- Sleep Studies
- Assisted Reproductive Technologies
- Out-of-Network Covered Services, except for Out-of-Network Emergency Services

Factors:

1. Clinical Appropriateness: the application of prior authorization supports optimal clinical outcomes
2. Value – ROI is defined as the value of using prior authorization exceeds the administrative costs
3. Variability is defined as the cost per episode of care is variable when compared to other services in the classification

Evidentiary Standards:

1. Clinical appropriateness is defined as services that internal clinical experts have determined should require authorization, based on evidenced-based clinical criteria and national, industry guidelines
2. Value – ROI is defined as the value of using prior authorization exceeds the administrative costs
3. Variability is defined as the cost per episode of care is variable when compared to other services in the classification

Sources:

1. Claims data
2. Operating costs
3. UM data
4. Expert clinical review
5. Evidence-based clinical criteria
6. Guidelines

CareFirst MIA MHPAEA NQTL Summary Form

Written Summary:

CareFirst BCBS performed a comparative analysis of the factors, evidentiary standards, and sources used in applying prior authorization to services for Medical/Surgical (M/S) and Mental Health and Substance Use (MH/SUD) "in-writing." Services require prior authorization as determined by internal clinical experts with appropriate expertise in M/S and MH/SUD. For both M/S and MH/SUD, medical experts inform these decisions using evidence-based clinical criteria and guidelines. In addition to expert opinion, a uniform process exists for evaluating M/S and MH/SUD services for inclusion in prior authorization. Claims data, operating costs, and utilization management data are leveraged to identify M/S and MH/SUD services where variation, or value in performing utilization management, are present. M/S and MH/SUD services are considered for prior authorization inclusion using the same factors, evidentiary standards, and source information, using the same process.

Outcome: There is only one process, one set of criteria, evidentiary standards, and sources used to consider M/S and MH/SUD services for prior authorization inclusion. Clinical determinations are performed by equally qualified clinicians for M/S and MH/SUD services; and both M/S and MH/SUD utilize evidence-based clinical criteria. Accordingly, it was determined that prior authorization is comparable and no more stringent in application for MH/SUD, than it is for M/S, in-writing.

Operational Summary:

CareFirst BCBS performs a comparative analysis "in-operation" for M/S and MH/SUD. The analysis includes review of prior authorization approval and denials, as well as appeals which may relate to any adverse decisions. The outcomes of the report support that the application of prior authorization is no more stringent for MH/SUD services than it is for M/S services, in-operation.

Concurrent Review Process

Description: Concurrent review is a component of CareFirst BCBS'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 encourages 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 may begin 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. A 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.

Factors:

1. Clinical Appropriateness: the application of prior authorization supports optimal clinical outcomes
2. Value – ROI is defined as the value of using prior authorization exceeds the administrative costs
3. Variability is defined as the cost per episode of care is variable when compared to other services in the classification

Evidentiary Standards:

CareFirst is currently in the process of defining specific numerical benchmarks to assist with illustrating the application of the factors:

1. Clinical appropriateness is defined as services that internal clinical experts have determined should require authorization, based on evidenced-based clinical criteria and national, industry guidelines
2. Value – ROI is defined as the value of using prior authorization exceeds the administrative costs
3. Variability is defined as the cost per episode of care is variable when compared to other services in the classification

Sources:

1. Claims data
2. Operating costs
3. UM data
4. Expert clinical review
5. Evidence-based clinical criteria
6. guidelines

Written Summary:

CareFirst BCBS performed a comparative analysis of the factors, evidentiary standards, and sources used in applying concurrent review to inpatient services for Medical/Surgical (M/S) and Mental Health and Substance Use (MH/SUD) "in-writing." Inpatient services require concurrent review as determined by internal clinical experts with appropriate expertise in M/S and MH/SUD. For both M/S and MH/SUD, medical experts inform these decisions using evidence-based clinical criteria and guidelines. In addition to expert opinion, a uniform process exists for evaluating M/S and MH/SUD services for inclusion in concurrent review. Claims data, operating costs, and utilization management data are leveraged to identify M/S and MH/SUD services where variation and or value in performing utilization management, are present. M/S and MH/SUD inpatient services are considered for concurrent review inclusion using the same factors, evidentiary standards, and source information, using the same process.

Outcome: There is only one process, one set of criteria, evidentiary standards, and sources used to consider M/S and MH/SUD services for concurrent review inclusion. Clinical determinations are performed by equally qualified clinicians for M/S and MH/SUD services; and both M/S and MH/SUD utilize evidence-based clinical criteria. Accordingly, it was determined that inpatient concurrent review is comparable and no more stringent in application for MH/SUD, than it is for M/S, in-writing.

Operational Summary

CareFirst BCBS performs a comparative analysis "in-operation" for M/S and MH/SUD. The analysis includes review of concurrent review approval and denials, as well as appeals which may relate to any adverse decisions. The outcomes of the report support that the application of concurrent review is no more stringent for MH/SUD services than it is for M/S services, in-operation.

Retrospective Review Process

Description: Retrospective review is a component of CareFirst BCBS's utilization management program. Only services that require prior authorization and/or concurrent review are eligible for retrospective review instead if prior authorization or concurrent review was not obtained.

Strategy: Inpatient Retrospective Review begins when CareFirst receives notification post-discharge that an inpatient hospitalization and/or emergency services occurred, and prior authorization of the services was not previously obtained when required. Outpatient Retrospective Review occurs when CareFirst receives notification that outpatient services were rendered, and prior authorization of the services was not previously obtained when required.

Process: Appropriate clinical staff will review the services rendered using evidence-based clinical guidelines. A 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.

Factors:

1. Clinical Appropriateness: the application of prior authorization supports optimal clinical outcomes
2. Value – ROI is defined as the value of using prior authorization exceeds the administrative costs
3. Variability is defined as the cost per episode of care is variable when compared to other services in the classification

Evidentiary Standards:

Clinical appropriateness is defined as services that internal clinical experts have determined should require authorization, based on evidenced-based clinical criteria and national, industry guidelines.

1. Clinical appropriateness is defined as services that internal clinical experts have determined should require authorization, based on evidenced-based clinical criteria and national, industry guidelines
2. Value – ROI is defined as the value of using prior authorization exceeds the administrative costs
3. Variability is defined as the cost per episode of care is variable when compared to other services in the classification

CareFirst MIA MHPAEA NQTL Summary Form

Sources:

1. Claims data
2. Operating costs
3. UM data
4. Expert clinical review
5. Evidence-based clinical criteria
6. guidelines

Written Summary:

CareFirst BCBS performed a comparative analysis of the factors, evidentiary standards, and sources used in applying retrospective review to services for Medical/Surgical (M/S) and Mental Health and Substance Use (MH/SUD) "in-writing." Services are subject to retro review as determined by internal clinical experts with appropriate expertise in M/S and MH/SUD. For both M/S and MH/SUD, medical experts inform these decisions using evidence-based clinical criteria and guidelines. In addition to expert opinion, a uniform process exists for evaluating M/S and MH/SUD services for inclusion in retrospective review. Claims data, operating costs, and utilization management data are leveraged to identify M/S and MH/SUD services where variation, or value in performing utilization management, are present. M/S and MH/SUD services are considered for retrospective review inclusion using the same factors, evidentiary standards, and source information, using the same process.
Outcome: There is only one process, one set of criteria, evidentiary standards, and sources used to consider M/S and MH/SUD services for retrospective review. Clinical determinations are performed by equally qualified clinicians for M/S and MH/SUD services; and both M/S and MH/SUD utilize evidence-based clinical criteria. Accordingly, it was determined that inpatient retrospective review is comparable and no more stringent in application for MH/SUD, than it is for M/S, in-writing.

Operational Summary:

CareFirst "Blue Cross Blue" Shield (BCBS) performs a comparative analysis "in-operation" for M/S and MH/SUD. The analysis includes review of retrospective review approval and denials, as well as appeals which may relate to any adverse decisions. The outcomes of the report support that the application of retrospective review is no more stringent for MH/SUD services than it is for M/S services, in-operation.

Pharmacy – Medical Necessity

Description: Medical Necessity means health care services or supplies that a health care 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 health care 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 health care 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 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.

The P&T Committee is foundational in the process. The P&T Committee is an external advisory body of experts from across the United States, composed of 22 independent health care professionals including 18 physicians and four pharmacists, all of whom have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the P&T Committee members are actively practicing pharmacists and physicians, including pediatric and adult psychiatrists.

Factors:

Methods used to determine if "*Medical Necessity*" is applied to a service:

1. Clinical Appropriateness
2. Clinical Effectiveness
3. Safety of Treatment

Evidentiary Standards:

The standards that indicate or trigger the factors:

1. FDA labelling
2. Peer reviewed clinical literature
3. Approved drug compendia
4. Clinical practice guidelines, consensus statements, or comparable publications
5. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references

Sources:

The sources used to define the factors and standards:

1. FDA labelling
2. Peer reviewed clinical literature
    a. E.g.: American Psychiatric Association, American Academy of Neurology
3. Approved drug compendia
4. Clinical practice guidelines, consensus statements, or comparable publications
    a. E.g.: Cochrane Database,
5. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
    a. E.g.: American Academy of Neurology
6. Appropriate clinical drug information from other sources as applicable
7. Package inserts, European Journal of Neurology

Written Summary:

When using the supplied factors to support the application of NQTLs to drugs on the formulary, more weight is given to FDA labeling and clinical guidelines, to ensure the NQTLs are clinically appropriate. During the process of developing and applying NQTLs to a given drug, all the above sources and evidentiary standards are reviewed to gather information about the drug, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These evidentiary sources provide the background information that is used when considering the factors that determine when an NQTL may be appropriate for the drug.

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 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.

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. There is one committee with oversight of all meds for M/S and MH/SUD, using the same processes.
The processes and strategies for developing and applying NQTLs to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying NQTLs to drugs used to treat MED/SURG conditions.

Operational Summary:

CVSC will routinely monitor aspects of utilization management as required by any applicable laws, regulations, accreditation requirements, or contractual obligations. These include, but are not limited to decision accuracy, clinical appropriateness, and cost effectiveness. Decision accuracy will be assessed by a Clinical oversight of pharmacist and physician decisions, in accordance with applicable CVS Caremark® policies and procedures b. Inter-rater reliability reviews, in accordance with applicable CVS Caremark® policies and procedures.
CVSC designates a Medical Director who will be responsible for managing the oversight evaluations of the UM case reviews.

Pharmacy – Tiering Formulary

Description: A formulary is a list of drugs covered by a plan offering prescription drug benefit. A formulary is sometimes referred to as a covered drug list. A tiered formulary is one that divides drugs into tiers that are ranked based on certain factors, such as cost, whether the drug is generic or brand, whether the product is considered preferred or non-preferred among others. The tiers on a formulary may determine the amount of cost share the member pays for a covered prescription drug.

Strategy: The formulary selection process includes a comparison of safety and effectiveness amongst similar drugs. Formulary decision making includes a variety of clinical considerations such as clinical indications, clinical evidence, adverse event profile, available dosage forms, dosing frequency, generic competition, and clinical adherence. In addition, drug and drug class appropriateness is considered when considering a drug for inclusion. The above considerations are used when making formulary decisions for all drug classes including all drugs used for MH/SUD and MED/SURG conditions.

Most drug classes have multiple generic and low-cost brand-name options that cover the same indications as more costly brand-name options in the same class. Often, the generic and low-cost brand-name options offer similar efficacy and safety. A tiering formulary is available to promote cost-effective use of medications. All formularies include generic drugs, which are typically in the lowest copay tier for members. Preferred brand-name drugs are encouraged with a lower copay than non-preferred brand-name products. Tiered benefit design encourages generic utilization and lowers pharmacy cost through copay differentials. The goal is to provide the lowest net cost to clients within each therapeutic class while ensuring that options available on our drug lists are consistent with current standards of practice and clinical guidelines.

Process: The Formulary Review Committee (FRC) is an internal CVS Caremark committee that evaluates changes that may affect formulary. For example, when two or more drugs provide similar clinical results, the FRC may evaluate factors such as: Utilization trend, impact of generic drugs or drug designated to become available over the counter, brand and generic pipeline, line of business, plan sponsor cost, applicable manufacturer agreements, potential impact on members. The FRC makes business recommendations based on such factors to the P&T Committee. It is important to note that any drug product must first be deemed safe and effective by the P&T Committee before it is considered eligible for inclusion on a CVS Caremark Formulary or Drug List, and that any recommendations made by the FRC must be approved by the P&T Committee before implementation.

The P&T Committee reviews all standard formularies annually. The review is conducted by drug class to assure that the formulary recommendations previously established are maintained and to recommend additional changes for clinical appropriateness if advisable based on

newly available pharmaceutical information. The resulting Formulary benefit design and copay tiering are applied consistently across all drugs and drug classes and do not discriminate against individuals based on medical or surgical condition, mental health or substance use disorder diagnosis, or other health conditions.

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 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.

Factors:

The methods used to determine if Tiering formulary is:

1. Regulatory Requirements:
2. Clinical Appropriateness E.g.
    a. Brand or generic status of the drug
    b. FDA approved uses
    c. Availability of therapeutic alternatives
    d. Manufacturer agreement
    e. Potential impact on members
3. Cost Effectiveness

Evidentiary Standards:

The standards that indicate or trigger the factors:

1. State and/or Federal Mandate
2. FDA product labelling
3. Nationally recognized and approved drug compendia
4. Consensus documents and nationally sanctioned guidelines
5. Publications of the National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and other organizations or government agencies

6. Evidence-based reviews of peer-reviewed medical literature and relevant clinical information
7. Standards of care recommended by clinical literature, medical or pharmacy societies, standard clinical drug references
8. Appropriate clinical drug information from other sources as applicable
9. Input from physicians practicing in the relevant clinical area
10. Professional opinions (external)
11. Publications by professional societies or government agencies
12. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
13. Appropriate clinical drug information from other sources as applicable
14. Brand/generic Pipeline.

Sources:

The sources used to define the factors and standards:

1. State and/or Federal Mandate
2. FDA product labelling
3. Nationally recognized and approved drug compendia
4. Consensus documents and nationally sanctioned guidelines
5. Publications of the National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and other organizations or government agencies
6. Evidence-based reviews of peer-reviewed medical literature and relevant clinical information
7. Standards of care recommended by clinical literature, medical or pharmacy societies, standard clinical drug references
8. Appropriate clinical drug information from other sources as applicable
   Input from physicians practicing in the relevant clinical area
9. FDA approved labelling
10. National clinical guidelines
11. IPD Analytics
12. Publications by professional societies or government agencies
13. Medispan/First Data Bank for pricing source
14. Manufacturer Trade Agreement
15. National Expert Panels with clinicians (MD, Pharmacist, Nurse) within the specific specialty

Written Summary:

When using the supplied factors to support the application of NQTLs to drugs on the formulary, more weight is given to FDA labeling and clinical guidelines, to ensure the NQTLs are clinically appropriate. During the process of developing and applying NQTLs to a given drug, all of the above sources and evidentiary standards are reviewed to gather information about the drug, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These evidentiary sources provide the background information that is used when considering the factors that determine when an NQTL may be appropriate for the drug.

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 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, 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. There is one committee with oversight of all meds for M/S and MH/SUD, using the same processes.
The processes and strategies for developing and applying NQTLs to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying NQTLs to drugs used to treat MED/SURG conditions. Data analysis of the NQTLs as applied to M/S and MH/SUD medications, further support that pharmacy NQTLs are no more stringently applied to MH/SUD medications, than to M/S medications:

Operational Summary:

The processes and strategies for determining tier placement for drugs used to treat MH or SUD conditions do not differ from the processes and strategies for drugs used to treat MED/SURG conditions. As shown, the analysis of the formulary data demonstrates that tier placement decisions for drugs in the MH/SUD drug classes and MED/SURG drug classes are based on the same factors. Analysis supports a similar application for M/S and MH, with all SUD medications appearing in the lower cost tiers. In conclusion, analysis demonstrated that in the determination of tier placement as an NQTL, the factors, processes, strategies, evidentiary standards, and sources identified above, are applied no more stringently MH/SUD than M/S, in operation.

Pharmacy – Step Therapy

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. Step therapy (ST) is a utilization management strategy typically employed in therapeutic classes with broad generic availability. Step therapy 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; with the potential for savings via increased utilization of generics and/or lower cost brands.

Process: 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 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.

Factors:

The methods used to determine if *"Step Therapy"* is applied:

1. Clinical safety and efficacy E.g.:
    - Clinical safety and adverse events based on FDA approved labelling and national clinical guidelines
    - Multiple dosage forms available for the same or similar chemical entities, or availability of unique dosage forms
    - Availability of therapeutic alternatives,
    - including generics, used to treat the same condition
2. Cost Effectiveness

Evidentiary Standards:

The standards that indicate or trigger the factors:

1. FDA approved labelling
2. National clinical guidelines
3. Drug Compendia
4. Peer reviewed literature
5. Trials and studies
6. Professional opinions (external)
7. Publications by professional societies or government agencies
8. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
9. Appropriate clinical drug information from other sources as applicable
10. Professional opinions (external)
11. Publications by professional societies
12. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
13. Appropriate clinical drug information from other sources as applicable
14. Brand/generic Pipeline

Sources:

The sources used to define the factors and standards:

1. FDA labelling
2. Peer reviewed clinical literature
    a. E.g.: American Psychiatric Association, American Academy of Neurology
3. Approved drug compendia
4. Clinical practice guidelines, consensus statements, or comparable publications
    a. E.g.: Cochrane Database,
5. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
    a. E.g.: American Academy of Neurology
6. Appropriate clinical drug information from other
7. sources as applicable

a. Package inserts, European Journal of Neurology

8. Professional opinion (external)
9. FDA approved labelling
10. National clinical guidelines
11. IPD Analytics
12. Publications by professional societies or government agencies
13. Medispan/First Data Bank for pricing source
14. Manufacturer Trade Agreement
15. National Expert Panels with clinicians (MD, Pharmacist, Nurse) within the specific specialty

Written Summary:

When using the supplied factors to support the application of NQTLs to drugs on the formulary, more weight is given to FDA labeling and clinical guidelines, to ensure the NQTLs are clinically appropriate. During the process of developing and applying NQTLs to a given drug, all the above sources and evidentiary standards are reviewed to gather information about the drug, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These evidentiary sources provide the background information that is used when considering the factors that determine when an NQTL may be appropriate for the drug.

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 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.

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. There is one committee with oversight of all meds for M/S and MH/SUD, using the same processes.
The processes and strategies for developing and applying NQTLs to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying NQTLs to drugs used to treat MED/SURG conditions. Data analysis of the NQTLs as applied to M/S and MH/SUD medications, further support that pharmacy NQTLs are no more stringently applied to MH/SUD medications, than to M/S medications:

Operational Summary:

The factors, processes, strategies, evidentiary standards, and sources, both as written and in operation, are applied no more stringently for step therapy and are consistent across all drugs and drug classes. Further analysis shows that step therapy is applied comparably to MH/SUD and MED/SURG drug categories.

Pharmacy – Quantity Limits

Description: Quantity Limits (QL) establish a maximum quantity of certain medications that will be covered over a specified time. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time, the amount covered for the drug, or the number of prescriptions claims for the drug over a period. Pharmacy quantity limits apply to both generic and brand drugs.

Strategy: Appropriate pharmacy quantity limits are applied to each drug class, and to generic and brand name medications, regardless of whether the intended use is for a MH/SUD condition or a M/S condition. Quantity limits are applied based on evidence-based clinical criteria, including FDA labeling and black box warnings. Use of appropriate pharmacy limits helps to prevent overutilization, abuse, misuse, and waste, while ensuring that dosing is consistent with clinical criteria. Providers and members may reference medications with quantity limits, by reviewing the drug formulary. In some cases, post-limit criteria may be available which allows prescribers to request additional quantities above the initial quantity limit when medical necessity criteria are met.

Process: The CVS P&T Committee is an external advisory body of expert members from a variety of medical specialties. The P&T committee has oversight of quantity limits and any clinical criteria, clinical program content, or utilization criteria related to the quantity limit. FDA labeling is followed. In addition, the P&T Committee reviews and approves QLs that are indicated based on additional sources of clinical criteria or guidance.

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 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.

Factors:

The methods used to determine if *"Quantity Limit"* is applied:

1. Enhance Patient Safety, e.g.:
2. Potential for a drug to be prescribed in greater quantities and/or at a higher dose than deemed safe and effective by the FDA
3. To promote appropriate drug dosing, including strength and frequency
4. To prevent overutilization
    a. when abuse or misuse by the patient is possible
5. For opioids and narcotics, when appropriate dosing and appropriate duration of use is based on treatment for acute or chronic pain

Evidentiary Standards:

The standards that indicate or trigger the factors:

1. FDA product labelling
2. Published peer-review clinical literature
3. Nationally recognized and approved drug compendia
4. Accepted clinical practice guidelines, consensus statements, or comparable publications
5. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
6. Appropriate clinical drug information from other sources as applicable

Sources:

The sources used to define the factors and standards:

1. FDA labelling
2. Peer reviewed clinical literature
    a. E.g.: American Psychiatric Association, American Academy of Neurology
3. Approved drug compendia
    a. Clinical practice guidelines, consensus statements, or comparable publications
    b. E.g.: Cochrane Database
    c. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
    d. E.g.: American Academy of Neurology

e. Appropriate clinical drug information from other sources as applicable
f. Package inserts, European Journal of Neurology

Written Summary:

When using the supplied factors to support the application of NQTLs to drugs on the formulary, more weight is given to FDA labeling and clinical guidelines, to ensure the NQTLs are clinically appropriate. During the process of developing and applying NQTLs to a given drug, all the above sources and evidentiary standards are reviewed to gather information about the drug, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These evidentiary sources provide the background information that is used when considering the factors that determine when an NQTL may be appropriate for the drug.

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 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).

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. There is one committee with oversight of all meds for M/S and MH/SUD, using the same processes.
The processes and strategies for developing and applying NQTLs to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying NQTLs to drugs used to treat MED/SURG conditions. Data analysis of the NQTLs as applied to M/S and MH/SUD medications, further support that pharmacy NQTLs are no more stringently applied to MH/SUD medications, than to M/S medications:

Operational Summary:

CareFirst preforms analysis of quantity limits for MH/SUD and M/S pharmaceuticals. The application of quantity limits is no more stringently applied to MH/SUD pharmaceuticals, than MS pharmaceuticals.

Pharmacy – Prior Authorization

Description: Prior assessment that prescribed medications are medically necessary, an appropriate treatment for a particular patient, and will be covered by the plan. 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 necessity 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 Plan terms and evidence-based clinical criteria. A coverage determination is rendered by licensed pharmacists in good standing and physicians who are who are board certified or eligible in the same specialty as the treatment under review. In accordance with state 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 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.

Factors:

The methods used to determine if Prior Authorization is applied

1. Clinical Appropriateness: The application of prior authorization supports optimal clinical outcomes and/or reduces risk. E.g.:
    a. Patient safety concerns with a drug or drug class; unknown long-term safety or durability
    b. Applicable lab values or other test results, or therapies required for appropriate treatment
    c. Appropriate medication uses for indications or conditions based on national guidelines; Use in appropriate patient populations
    d. Potential for inappropriate or off-label use
    e. Opportunity for optimizing patient outcomes and to ensure treatment goals of the drug are being met
2. Cost Effectiveness E.g.:
    a. Plan sponsor costs / lowering client cost when clinically appropriate

Evidentiary Standards:

The standards that indicate or trigger the factors:

1. FDA product labelling
2. Published peer-review clinical literature
3. Nationally recognized and approved drug compendia
4. Accepted clinical practice guidelines, consensus statements, or comparable publications
5. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
6. Appropriate clinical drug information from other sources as applicable

Sources:

The sources used to define the factors and standards:

1. FDA labelling
2. Peer reviewed clinical literature
    a. E.g.: American Psychiatric Association, American Academy of Neurology
3. Approved drug compendia
4. Clinical practice guidelines, consensus statements, or comparable publications
    a. E.g.: Cochrane Database,

5. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
    a. E.g.: American Academy of Neurology
6. Appropriate clinical drug information from other
7. sources as applicable
    a. Package inserts, European Journal of Neurology
8. Professional opinion (external)
9. FDA approved labelling
10. National clinical guidelines
11. IPD Analytics
12. Publications by professional societies or government agencies
13. Medispan/First Data Bank for pricing source
14. Manufacturer Trade Agreement
15. National Expert Panels with clinicians (MD, Pharmacist, Nurse) within the specific specialty

Written Summary:

When using the supplied factors to support the application of NQTLs to drugs on the formulary, more weight is given to FDA labeling and clinical guidelines, to ensure the NQTLs are clinically appropriate. During the process of developing and applying NQTLs to a given drug, all the above sources and evidentiary standards are reviewed to gather information about the drug, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These evidentiary sources provide the background information that is used when considering the factors that determine when an NQTL may be appropriate for the drug.

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 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).

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. There is one committee with oversight of all meds for M/S and MH/SUD, using the same processes.

The processes and strategies for developing and applying NQTLs to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying NQTLs to drugs used to treat MED/SURG conditions. Data analysis of the NQTLs as applied to M/S and MH/SUD medications, further support that pharmacy NQTLs are no more stringently applied to MH/SUD medications, than to M/S medications:

Operational Summary:

CareFirst preforms analysis of prior authorization for MH/SUD and M/S pharmaceuticals. The application of prior authorization is no more stringently applied to MH/SUD pharmaceuticals, than MS pharmaceuticals.

Process for Assessment of New Technologies

Description: Technology assessments are a structured analysis of a technology, drug, or treatment that is performed for the purpose of providing input to clinical policy. Technology assessments include an examination of safety, efficacy, feasibility outside of the investigational setting, comparability to existing technologies relative to outcomes, indications for use, as well as 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 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 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 Committee reviews scientific evidence and outcomes from randomized control trials, observational studies, and safety surveillance. The Committee'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, or Legal. Submitters may include but are not limited to 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. When a new or evolving technology is identified.

We maintain a comprehensive database of content related to genetic disease and genetic testing technology. All guidelines are formally updated semi-annually, with off-cycle revisions to coverage criteria triggered by publication of new literature, professional society guidelines and supporting evidence. Subject matter experts perform quarterly research scoping to identify new evidence for review and incorporation into the published guidelines. Because our division is also reviewing preauthorization requests in real time, we are tuned to clinician ordering patterns and have visibility into potential areas of abuse. Additionally, transparent and accessible mechanisms are in place for subject matter experts to receive and evaluate feedback from clinical providers and laboratories. Finally, editorial safeguards are in place to reduce the need for updates at market adjustments by avoiding specific proprietary test names when able and instead focusing on the validated testing methods.

Factors:

1. Member, Provider or Other submission of clinical evidence
2. CareFirst– new evidence identified during routine clinical research or medical policy review

Evidentiary Standards:

1. Clinical efficacy of the technology:
    a. The technology yields an improvement in health outcomes as detailed within clinical evidence
    b. When compared to alternative treatments, health outcomes are improved with use of the new technology, as detailed within clinical evidence
2. Safety of the new technology including:
    a. App Benefits of the proposed technology outweigh harmful effects
    b. Approval from the appropriate U.S government regulatory bodies, if applicable
3. Appropriateness of the new technology including:
    a. Improvements are attainable outside of the investigational setting

Sources:

1. Clinical evidence (scientifically based) E.g.:
    a. FDA
    b. Hayes
    c. Cochrane Library
    d. Centers for Medicare & Medicaid Services

   e. National Institute of Health U.S. National Library of Medicine
   f. MCG, ACG, LCDs, NCDs
   g. NCCN
   h. PubMed
   i. UpToDate
2. Peer reviewed literature
3. Systematic reviews
4. Trials (randomized, controlled)
5. Studies (comparative, cohort, cross-sectional, retrospective, surveillance)
6. Case reviews
7. Editorials
8. Professional and association opinions

Written Summary:

CareFirst conducts analysis to determine if the strategy, process, standards, and source information used to conduct Assessments of New Technology are comparable and not more stringently applied to MH/SUD technology than to M/S technology. The same TAC committee, using the same process, relevant clinical expertise, factors, evidentiary standards, and clinical sources (hierarchy of evidence) are used for New Technology assessments of M/S and MH/SUD. CareFirst concludes that New Technology assessments are comparable to and not more stringent for MH/SUD than M/S, in writing.

Operational Summary:

CareFirst performed an analysis of New Technology Assessments in operation. The volume of all assessments, as well as the outcome of all assessments does not represent sample sizes sufficient for robust analysis. Despite this, the available information does make evident that M/S and MH/SUD technology assessments are readily available using the same process, factors, evidentiary standards, and sources. No disparity exists in CareFirst's Assessment of New Technology; rather the disparity is inherent in the ratio of M/S and MH/SUD New Technology, which becomes available to review. Accordingly, CareFirst finds that Assessment of New Technology is comparable and no more stringent for M/S than MH/SUD, in operation.

In partnership with CareFirst, CVS Caremark has provided the following information for Assessment of New Technologies:

Pharmacy - CVS Caremark

Patients can manage all their specialty medications in real time using the CVS Specialty app or website. The team is continually innovating to meet the evolving dynamics of the market, and helping clients improve the health and outcomes of their members with specialty conditions and look far enough out to develop unique solutions, but not so far out that exciting concepts outrun the science or technology. The team is piloting, testing, and developing several solutions.

- **Implementation to scale:** Expansion of the multiple sclerosis wearables program
- **In pilot:** Remote monitoring app for hemophilia to collect real-time patient data on bleeds, infusions, quality of life, and possible deviations from normal for the patient
- **In testing:** Specific biomarker tests in autoimmune disease and tumor-specific genomic profiling as tools to inform the best course of treatment
- **In development:** Predictive analytics to identify barriers to adherence so we can provide more effective and proactive interventions

CVS Specialty uses app data of participating members to collect and analyze the new technology. For example, CVS Specialty is expanding pilot which uses a wearable device to monitor multiple sclerosis member activity levels over time to identify early signs of disease progression and monitor for suboptimal or ineffective therapies. The device offers symptom monitoring and a walk test which tracks trends in mobility, balance, and new or worsening symptoms. Data captured by the wearable and companion app is shared with the participating member's care team to inform their care management conversations and support timely interventions and optimal member outcomes. With these insights, we are looking to understand whether these tools improve the patient experience, enhance clinical care, and manage cost and trend when we intervene.

Leveraging learnings and technology from the multiple sclerosis wearables pilot, CVS Specialty is piloting a remote monitoring app that enables a hemophilia patient to digitally record bleeds, infusions, symptoms, and manage their medication inventory. The app captures in real time patient-reported outcomes data related to bleeds, infusions, unplanned medical visits, and quality of life, and alerts the care team to any possible deviations from normal.

Data can then be used by the Pharmacy Care Team to:

- Intervene in a timely manner upon exacerbations or unexpected health care visits
- Improve treatment compliance and reduce medication waste
- Improve patient safety through contextual recall alerts

Remote monitoring technology has the potential to connect all a patient's providers, including their physician, pharmacy care team, and nursing teams. It also provides a digital way to monitor and provide adherence visibility to empower patients and caregivers.

In partnership with CareFirst, Carelon Medical Benefits management (Carelon) has provided the following information for Assessment of New Technologies:

Genetic Testing -The Carelon Medical Benefits Management

On behalf of CareFirst, Carelon manages the utilization management process for genetic test used to assess medical, mental health, and substance use disorder. The fundamental framework for reviewing genetic tests does not vary by the disease category, although the guidelines themselves may be organized by certain categories. The Carelon IDNA genetic testing guidelines are organized by types/categories of genetic testing as applied in clinical practice.

The current categories include:

- Genetic Testing for Single-Gene and Multifactorial Conditions
- Genetic Testing for Hereditary Cancer Susceptibility
- Genetic Testing for Hereditary Cardiac Disease
- Pharmacogenomic and Thrombophilia Testing
- Reproductive Carrier Screening and Prenatal Diagnosis
- Somatic Tumor Testing
- Whole Exome and Whole Genome Sequencing

Genes relevant to mental health disorders encompass a wide range of conditions however, currently available genetic testing for mental health disorders would typically fall under the guidelines for genetic testing for single-gene and multifactorial conditions (GT01) which has specific criteria for germline genetic testing and for multifactorial (Non-Mendelian) genetic testing; or pharmacogenomic testing (GT 06) where the focus is on criteria for use of single gene or multi-gene pharmacogenomic assays predicting treatment response or toxicity related to drug therapies for mental health disorders.

The Carelon IDNA guidelines are based on medical evidence associated with the genetic tests. The overall evidence review process is based on the CDC ACCE Framework for Clinical Utility and includes reviewing evidence related to four critical criteria: 1) analytic validity; 2) clinical validity; 3) clinical utility; and 4) ethical, legal, and social implications. Targeted areas of interest including specific characters of the genetic disorder, quality of clinical validation, potential intervention and outcomes, and ethical and socioeconomic considerations.
The evidentiary review process of primary literature is based on the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) working group and the Agency for Healthcare Research and Quality (AHRQ) evidence evaluation recommendations. This includes an assessment of clinical utility, clinical validity (incorporating prevalence, penetrance, and expressivity), potential harms and recommended algorithms for genetic testing. When warranted more detailed assessment addressing analytic validity, incorporating laboratory quality control (QC) factors (e.g., platform/assay used, test sensitivity and specificity, variant classification methods, laboratory-specific quality control processes, and report quality) is included.

Standards for Provider Credentialing and Contracting

Description: CareFirst has one credentialing plan. Credentialing requirements and standards apply equally to M/S and MH/SUD professional providers (MD), M/S and MH/SUD professional providers (non-MD), and to M/S and MH/SUD institutional and ancillary providers and facilities. Please note the CareFirst Medical Provider Manual applies to both M/S and MH/SUD providers and facilities.

Factors:
Credentialing "non-weighted" Factors (applies to all In-Network classifications, M/S and MH/SUD). The implicated factor which is used to determine that credentialing applies to a service:

1. Provider submits a completed application and attestation
2. CareFirst validation of information provided within the application
3. Monitoring: ensuring providers continue to meet credentialing requirements

4. Recredentialing every 3 years

Evidentiary Standards:

The following *"Evidentiary Standards"* marked with an " * " occur ongoing maintenance and or every 3 years:

1. Completed application and attestation is received
2. CareFirst BCBS provider manual
3. NCQA standards
4. State or federal requirements
5. CAQH application, facility application, or state application, as applicable
6. CareFirst questionnaire
7. Provider attestation
8. Required documentation
9. * State licensing boards, OIG, CAQH, NCQA standards, State, or federal requirements

Sources:

The following *"Sources"* marked with an " * " occur ongoing maintenance and or every 3 years:

1. Documents within CAQH application, facility application and/or supplemental documentation if not uploaded to CAQH
2. Provider attestation
3. CareFirst questionnaire
4. CAQH application, facility application, or state application, as applicable
5. State or federal requirements
6. NCQA standards
7. CareFirst BCBS provider manual
8. * State licensing boards, OIG, CAQH, NCQA standards, State, or federal requirements

Written Summary:

CareFirst uses the same process, factors, evidentiary standards, and sources when conducting M/S or MH/SUD provider credentialing. Credentialing staff follow the CareFirst BCBS credentialing plan (Provider Manual: Provider Network Requirements) https://provider.carefirst.com/carefirst-resources/provider/pdf/provider-manual-chapter-3-administrative-functions.pdf, NCQA standards and state or federal requirements as applicable. The requirements for credentialing are the same for M/S and MH/SUD. The only difference in requirements is related to whether a provider is a MD, or non-MD. For example, MD's require additional validation for DEA licensing, which does not exist for non-MD's (only required for prescribers).

However, credentialing requirements relevant to MDs or Non-MDs are consistently applied to both M/S and MH/SUD providers, without exception. All providers are subject to continual monitoring and credentialing every 3 years, consistent with CAQH and state standards. CareFirst examined the process, factors, evidentiary standards, and sources used for all providers and facility credentialing and determined that the process, factors, evidentiary standards, and sources used to credential MH/SUD providers is no more stringent than the process, factors and evidentiary standards used to credential M/S providers, in writing.

Operational Summary:

CareFirst only has one credentialing process, department, and committee, as well as one set of factors, evidentiary standards, and sources, applied to both M/S and MH/SUD providers, and facilities seeking to join the network. CareFirst performs analysis of provider and facility credentialing. Analysis includes all credentialing outcomes: providers and facilities credentialed and added to the network, applications withdrawn, and applicants rejected/denied. The outcomes of analysis support that MH/SUD credentialing practices are no more stringently applied.

Reimbursement for INN Providers, OON Providers, INN Facilities, OON Facilities, Emergency

Description: Carefirst's NQTL model for In and Out of Network Reimbursement(s) follows mandates provided by the state & the Consolidated Appropriations Act (CAA). When state methodology applies or Qualified Payment Amount (QPA) applies, no other factor applies.

Factors:

1. Provider Type(s): Specialty, license type, board certification, education, relevant training
2. Services provided
3. CMS RVUs
4. Market rates/geographic location
5. Network need
6. Patient volume/group size
7. SIU activity (FWA)
8. Provider quality outcomes

Evidentiary Standards:

1. Provider's specialty, license type, board certification, education, training, and experience is assessed
2. (Work RVU x work GPCI) + (PE RVU x PE GPCI) + (MP RVU x MP GPCI) x CF = CMS benchmark rate
    a. The Work RVU reflects the relative time and intensity associated with furnishing
    b. The Practice Expense (PE) RVU reflects the costs of maintaining a practice
    c. The Malpractice (MP) RVU reflects the costs of malpractice insurance
    d. Geographic Practice Cost Indices (GPCIs) geographic variations in the costs of practicing medicine in different areas of the country
    e. Conversion Factor (CF) the sum of the geographically adjusted RVUs by a CF in dollars.
3. Corresponding HCPC and CPT codes
4. Applicable market rates for the services based on geographic location
5. An identified network gap
6. Size of patient volume or size of the practice (number of providers in the group) may need to be considered
7. CareFirst SIU data
8. CareFirst quality data
9. Provider's specialty, license type
10. Inpatient, acute, ambulatory
11. rate agreement with state for OON emergency care, per Consolidated Appropriations Act

Sources:

1. Provider application, CAQH
2. Most current version of code sets
3. CMS RVU's
4. Provider application, external market rates i.e., Truvern Health Analytics
5. Geo access reporting, OON utilization, Member complaints specific to network adequacy
6. Claims data, Provider directory, Provider application and affiliations
7. CareFirst SIU data
8. CareFirst quality data
9. Claims
10. Most current version of code sets
11. CMS RVU's
12. Place of service, external market rates i.e., Truvern Health Analytics
13. Facility application
14. State agreement, rate based on 100% in-network rates

Written Summary:

There are no factors, evidentiary standards or sources applied to MH/SUD, which are not also applied to M/S. Both would follow the same hierarchy; if a state facility, payment methodology would follow state requirements. If not a state facility, or if a provider, the shared factors, evidentiary standards, and sources would be applied in setting standard rates, as well as in negotiating contracts. Accordingly, CareFirst finds that Reimbursement is no more stringently applied to MH/SUD, than to M/S, in writing.

Providers

CareFirst develops and maintains a standard fee schedule for use with M/S and MH/SUD providers, applied to both INN and OON providers. The fee schedule is updated through ongoing evaluation and maintenance, (e.g., AMA code additions/deletions), with adjustments/modifications typically once a year. In evaluating the standard fee schedule, CareFirst's methodology includes Medicare rates as the primary source. Medicare 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.

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 is able to share a desired fee schedule arrangement, based on competitive rates offered to them. Competitive market data would be considered by CareFirst. If an already contracted provider wishes to re-negotiate their contract, in addition to the above methodologies, CareFirst would also evaluate the provider's SIU activity (Fraud, Waste and Abuse), and provider quality results.

Facilities

CareFirst applies the state rate methodology to inpatient-acute and other facilities as required. When a facility is contracted via the state, no additional factors are applied in determining reimbursement and no negotiations occur. For facilities that are not contracted via the state, the same factors, evidentiary standards, and sources apply for both M/S and MH/SUD. In many circumstances, the facility provides both M/S and MH/SUD services and the contracts would be negotiated using the same methodology. When a facility provides only M/S or MH/SUD services, the same factors, evidentiary standards, and sources still apply, using CMS relatives as well as 3rd-party market rates, to ensure comparability.

Operational Summary:

CareFirst performs analysis of provider and facility reimbursement. In analysis, MS and MH/SUD reimbursement is evaluated in comparison to CMS benchmarks respectively. Overall, MS and MH/SUD reimbursement is evaluated, in addition to a more specific analysis using comparable services. Comparability is consistent between all M/S and MH/SUD reimbursement values, including for out-of-network providers. Accordingly, the process, strategy, factors, evidentiary standards, and sources used for MH/SUD provider reimbursement are no more stringent than the process, strategy, factors, evidentiary standards, and sources used for M/S reimbursement. CareFirst finds that reimbursement is no more stringently applied to MH/SUD, than in M/S, in operation.