



Coverage Exception Net Results

OBJECTIVE

These criteria apply to any request for agents that are included in the clients Lockout/Excluded Agents list and is not otherwise excluded from coverage under the member's pharmacy benefit.

For any agent which has additional clinical review criteria specific to the agent and/or disease state/medical condition, the additional clinical review criteria will also be applied.

CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval				
	A coverage exception will be granted when BOTH of the following are met: - The requested agent is NOT restricted for coverage under the patient's medical benefit AND<table border="1"><thead><tr><th colspan="2">Products Restricted to Medical Benefit</th></tr></thead><tbody><tr><td>For ALLIANT only</td><td>Intrauterine devices (Products with a dosage form of IUD)</td></tr></tbody></table> - ONE of the following: - ALL of the following: - The requested agent is in an Affordable Care Act (ACA) Preventive Care category AND - The member's benefit includes ACA Preventive Care for the category requested AND - ONE of the following: - The request agent is an aspirin agent AND ALL of the following: - The requested agent is the 81 mg strength aspirin AND - There is support that the requested aspirin agent is medically necessary AND - The patient is pregnant, at high risk of preeclampsia, and using the requested agent after 12 weeks of gestation OR - The requested agent is a bowel prep agent AND ALL of the following: - There is support that the requested bowel prep agent is medically necessary AND - The requested agent will be used for the preparation of colorectal cancer screening using fecal occult blood testing, sigmoidoscopy, or colonoscopy AND - The patient is 45 years of age or over OR - The requested agent is a breast cancer primary prevention agent AND ALL of the following: - There is support that the requested breast cancer primary prevention agent is medically necessary AND - The requested agent is tamoxifen, raloxifene, or an aromatase inhibitor (anastrozole, exemestane, letrozole) AND - The patient is 35 years of age or over AND - The agent is requested for the primary prevention of breast cancer AND - ONE of the following: - The plan has not implemented a sex requirement OR - The plan has implemented a sex requirement AND ONE of the following:	Products Restricted to Medical Benefit		For ALLIANT only	Intrauterine devices (Products with a dosage form of IUD)
Products Restricted to Medical Benefit					
For ALLIANT only	Intrauterine devices (Products with a dosage form of IUD)				

Module	Clinical Criteria for Approval
	1. The patient's sex is female OR 2. The requested agent is medically appropriate for the patient's sex OR D. The requested agent is a contraceptive agent AND BOTH of the following: 1. There is support that the requested contraceptive agent is medically necessary AND 2. The requested agent is being used for contraception OR E. The requested agent is a fluoride supplement AND BOTH of the following: 1. There is support that the requested fluoride supplement is medically necessary AND 2. The patient is 6 months to 16 years of age OR F. The requested agent is a folic acid agent AND ALL of the following: 1. There is support that the requested folic acid supplement is medically necessary AND 2. The requested folic acid supplement contains 0.4-0.8 mg of folic acid AND 3. The requested folic acid supplement is to be used in support of pregnancy AND 4. ONE of the following: A. The plan has not implemented a sex requirement OR B. The plan has implemented a sex requirement AND ONE of the following: 1. The patient's sex is female OR 2. The requested agent is medically appropriate for the patient's sex OR G. The requested agent is an Human Immunodeficiency Virus (HIV) infection pre-exposure prophylaxis (PrEP) agent AND ALL of the following: 1. There is support that the requested HIV PrEP agent is medically necessary AND 2. The requested agent is being used for HIV PrEP AND 3. The requested HIV PrEP agent is ONE of the following: A. Tenofovir disoproxil fumarate and emtricitabine combination ingredient agent OR B. Tenofovir alafenamide and emtricitabine combination ingredient agent OR C. Cabotegravir OR D. Yeztugo (lenacapavir) AND 4. The patient has increased risk for HIV infection AND 5. The patient has recently tested negative for HIV OR H. The requested agent is an infant eye ointment AND ALL of the following: 1. There is support that the requested infant eye ointment is medically necessary AND 2. The patient is 3 months of age or younger AND 3. The requested agent is requested for the prevention of gonococcal ophthalmia neonatorum OR I. The requested agent is an iron supplement AND ALL of the following: 1. There is support that the requested iron supplement is medically necessary AND 2. The patient is under 12 months of age AND 3. The patient is at an increased risk for iron deficiency anemia OR J. The requested agent is a statin AND ALL of the following: 1. There is support that the requested statin is medically necessary AND 2. The requested statin is for use in the primary prevention of cardiovascular disease (CVD) AND 3. The patient is 40-75 years of age (inclusive) AND 4. The patient has at least one of the following risk factors:

Module	Clinical Criteria for Approval
	A. Dyslipidemia B. Diabetes C. Hypertension D. Smoking AND 5. The patient has a calculated 10-year risk of a cardiovascular event of 10% or greater per the American College of Cardiology and American Heart Association's Atherosclerotic Cardiovascular Disease (ASCVD) calculator OR K. The requested agent is a tobacco cessation agent AND BOTH of the following: 1. The patient is a non-pregnant adult AND 2. ONE of the following: A. The requested tobacco cessation agent is not covered on a \$0 Affordable Care Act (ACA) list AND BOTH of the following: 1. There is support that the requested tobacco cessation agent is medically necessary AND 2. ONE of the following: A. The patient has received less than 180 day supply of the requested tobacco cessation agent type (e.g., NRT, bupropion, varenicline) in the past 365 days OR B. The patient has received 180 or more day supply of the requested tobacco cessation agent type (e.g., NRT, bupropion, varenicline) in the past 365 days AND ONE of the following: 1. The patient is currently being treated with the requested tobacco cessation agent type (e.g., NRT, bupropion, varenicline) and the patient is expected to be successful on this course of therapy [patient will be approved for remainder of up to a 24-week course] OR 2. There is support for the anticipated success of repeating therapy with the requested tobacco cessation agent type (e.g., NRT, bupropion, varenicline) [patient will be approved for an additional 24-week course of therapy] OR B. The requested tobacco cessation agent is covered on a \$0 Affordable Care Act (ACA) list AND ONE of the following: 1. The patient has received more than 180 day supply of the requested tobacco cessation agent type (e.g., NRT, bupropion, varenicline) in the past 365 days AND ONE of the following: A. The patient is currently being treated with the requested tobacco cessation agent type (e.g., NRT, bupropion, varenicline) and is expected to be successful on this course of therapy [patient will be approved for remainder of a 24-week course] OR B. There is support for the anticipated success of repeating therapy with the requested tobacco cessation agent type

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	(e.g., NRT, bupropion, varenicline) [patient will be approved for an additional 24-week course of therapy] OR L. The requested agent is a vaccine AND BOTH of the following: - There is support that the requested vaccine is medically necessary AND - The requested vaccine will be used per the recommendations of the Advisory Committee on Immunization Practices/CDC OR B. ALL of the following: - ONE of the following: - The requested agent is in an ACA Preventive Care category AND did NOT meet the preventive service requirements OR - BOTH of the following: - ONE of the following: - The requested agent is NOT in an ACA Preventive Care category OR - The member's benefit does NOT include ACA Preventive Care for the category requested AND - The requested agent is not excluded from coverage under the pharmacy benefit AND - The patient has an FDA labeled indication, or an indication supported in AHFS, DrugDex with 1 or 2a level of evidence, or NCCN with 1 or 2a level of evidence for the requested agent AND - ONE of the following: - The requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent AND ALL of the following (one agent may satisfy multiple requirements below): - If the requested agent is a brand product with an available formulary generic equivalent, then ONE of the following: - The patient has tried and had an inadequate response to one or more available formulary generic equivalent to the requested agent OR - There is support that ALL available formulary (any formulary tier) generic equivalent to the requested agent are contraindicated, likely to be less effective, or will cause an adverse reaction or other harm for the patient that is NOT expected to occur with the requested brand agent AND - If there is a formulary biosimilar agent(s) available for the requested agent, then ONE of the following: - The patient has tried and had an inadequate response to at least three (or as many as available, if fewer than three) of the available formulary biosimilar agent(s) with at least a 3 month trial OR - There is support that ALL available formulary biosimilar agent(s) are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient that is NOT expected to occur with the requested agent AND - ONE of the following - The patient has tried and had an inadequate response to at least two formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent OR - There is support that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient OR - The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent OR

Module	Clinical Criteria for Approval
	C. The prescriber states that the patient is currently receiving the requested agent (starting on samples is not approvable) and is at risk if the therapy is changed ACA Length of Approval: - Aspirin 81 mg: 9 months - Infant eye ointment: 3 months - All other indications: 12 months - Apply \$0 copay if ACA criteria met Coverage Exception length of approval: 12 months

CLINICAL CRITERIA OPERATIONAL LEVEL OF EVIDENCE REQUIREMENTS

Module	Ops Set Up	Validation Options	Other Explanation
	Validation: Apply Baseline and go to Validation Options	Age Verification;Diagnosis;Other (see Other explanation field)	*Review Info: The requested agent is NOT restricted for coverage under the patient's medical benefit *Review Info: There is support that the requested agent is medically necessary *Review Info: The requested aspirin agent is 81 mg aspirin *Review Info: The requested breast cancer prevention agent is tamoxifen, raloxifene, or an aromatase inhibitor (anastrozole, exemestane, letrozole) *Review Info: The requested folic acid supplement contains 0.4-0.8 mg of folic acid *Review Info: For tobacco cessation agent requests: **Review Info: The patient is currently being treated with the requested tobacco cessation agent type (e.g., NRT, bupropion, varenicline) and there is support that the patient is expected to be successful on this course of therapy **Review Info: There is support for anticipated success of repeating therapy with the requested tobacco cessation agent type (e.g., NRT, bupropion, varenicline) *Review Info: The requested agent is medically appropriate for the patient's sex *Review Info: The requested agent is not excluded from coverage under the pharmacy benefit *Review Info: If the requested agent is a brand product: **Review Info: Availability of a generic equivalent **Review Info: The patient has tried and had an inadequate response to one or more available formulary generic equivalent to the requested agent *Review Info: Availability of a biosimilar agent **Review Info: The patient has tried and had an inadequate response to at least three (or as many as available, if fewer than three) of the available formulary biosimilar agent(s) with at least a 3 month trial

Module	Ops Set Up	Validation Options	Other Explanation
			*Review Info: If the requested agent has formulary alternatives (any formulary tier) for the diagnosis being treated by the requested agent alternatives **Review Info: Availability of formulary alternatives **Review Info: The patient has tried and had an inadequate response to at least two formulary alternatives (any formulary tier), if available, for the diagnosis being treated with the requested agent *Review Info: There is support that ALL available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient *Review Info: The requested agent does NOT have formulary (any formulary tier) alternatives for the diagnosis being treated with the requested agent *Review Info: The prescriber states that the patient is currently receiving the requested agent (starting on samples is not approvable) and is at risk if the therapy is changed

DOCUMENT HISTORY

Approval Date MM/YYYY	Approved By	Notes
-		Original Prime Standard criteria approved by P&T UM Committee 07/2015 Annual Review Prime Standard criteria, with changes approved by P&T UM Committee 10/2015 Annual Review Prime Standard criteria, with changes approved by P&T UM Committee 10/2016 Annual Review Prime Standard criteria, with changes approved by P&T UM Committee 10/2017 Annual Review Prime Standard criteria, with changes approved by P&T UM Committee 09/2018 Mid-Year Review Prime Standard criteria, with changes, approved by P&T UM Committee 12/2018 Mid-Year Review Prime Standard criteria, with changes, approved by P&T UM Committee 06/2019 Annual Review Prime Standard criteria, with changes, approved by P&T UM Committee 09/2019 Annual Review Prime Standard criteria, with changes, approved by P&T UM Committee 09/2020 Mid-Year Review Prime Standard criteria, with changes, approved by P&T UM Committee 06/2021 Annual Review Prime Standard criteria maintained, approved by P&T UM Committee 09/2021 Mid-Year Review Prime Standard criteria, with changes to criteria, approved by P&T UM Committee 05/2022 Annual Review Prime Standard criteria, with changes to criteria, approved by P&T UM Committee 08/2022 Mid-Year Review Prime Standard criteria, with changes to criteria, approved by P&T UM Committee 02/2023 Annual Review Prime Standard criteria, with changes to criteria, approved by P&T UM Committee 08/2023
11-2023	P&T UM Committee	Mid-Year Review of Prime Standard criteria, with changes to criteria.
11-2023		Administrative Action (update of ops box vaccine products)
7-2024		Administrative Action (addition of Dengue and Mpox vaccines to ops box)
1-2025	P&T UM Committee	Annual Review of Prime Standard criteria, with changes to criteria
2-2025		Administrative Action (addition of weight loss note)
2-2025		Administrative Action (addition of weight loss note for additional health plan)
5-2025		Administrative Action (added MSC O is formulary exception for Alliant)
10-2025		Administrative Action (added Alliant verbiage for medical)
1-2026	P&T UM Committee	Annual Review of Prime Standard criteria, with changes to criteria.

NOTES FOR OPERATIONS

CO Notes	Date Created	Last Date ANY Field Changed
CR - historical note - *In letter, refer provider/member to the medical benefit if the request for a drug/drug class/medical condition is restricted to coverage under the Medical Benefit *If ACA criteria met, apply \$0 copay *Vaccines included in ACA: **COVID-19	08-26-2025 06:02:10 PM	

CO Notes	Date Created	Last Date ANY Field Changed
**Dengue Fever **Diphtheria-Tetanus Combinations (Toxoids) **Haemophilus Influenzae Type B (HIB) **Hepatitis A **Hepatitis B **Hepatitis Combinations **Human Papillomavirus (HPV) **Influenza **Measles, Mumps, and Rubella Virus (MMR) **Measles, Mumps, Rubella and Varicella (MMRV) **Meningitis **Mpox **Pneumonia **Polio **Respiratory syncytial virus (RSV) **Rotavirus **Shingles **Varicella (Chickenpox)		

Operational Table	
The requested agent is not excluded from coverage under the pharmacy benefit	
Products Excluded from the Pharmacy Benefit	
Drug Category	Bucket/Tier/How to identify
Surgical supplies/Medical Device/ Ostomy (Except for FreeStyle Libre sensor and reader)	Third Party Restriction Code 3 Please note that Hormel considers Omnipod products a formulary exception. These products should NOT be excluded as a benefit exclusion for Hormel (97201030506400, 97201030506300).
Diagnostic Agents (Except for diabetic test strips)	Third Party Restriction Code 5
General Anesthetics	Third Party Restriction Code 6
Bulk Powders	Third Party Restriction Code B
Cosmetic Agents	Third Party Restriction Code C
Route of Administration	Included on Tier 40 of FID 33102
Institutional Packs (Including diabetic test strips)	Identified through the modifier codes in the product detail (AAAD31, BBAD9A, TTAAJQ, TTAA5V, AAAB9A, AAADQQ, AAAD6T)
Clinical Packs	Clinic Pack field =Y
Repackagers	Repackager field =Y

Operational Table

AHFS Devices and Pharmaceutical Aids (Except for FreeStyle Libre sensor and reader)	AHFS code 940000000 (DEVICES) and/ or 960000000 (PHARMACEUTICAL AIDS) Please note that Hormel considers Omnipod products a formulary exception. These products should NOT be excluded as a benefit exclusion for Hormel (97201030506400, 97201030506300).
Medical Devices Approved through a different FDA Approval than Drugs	Included on FID 0298 Please note that Hormel considers Omnipod products a formulary exception. These products should NOT be excluded as a benefit exclusion for Hormel (97201030506400, 97201030506300).
Medical Devices and Supplies (Except for FreeStyle Libre sensor and reader)	GPI 97*, unless on the covered drug list Please note that Hormel considers Omnipod products a formulary exception. These products should NOT be excluded as a benefit exclusion for Hormel (97201030506400, 97201030506300).
New to Market FDA Approved Drugs	Included on FID 00214 Tiers 1, 2, & 3 = Formulary Exclusions Tiers 4, 5, & 6 = Benefit Exclusions
Non-FDA Approved Drugs	Included on FID 0220
OTC Medications (Rx-OTC indicator or O or P, unless on the covered drug list or eligible for coverage as part of the Affordable Care Act (ACA)) (Except for diabetic test strips)	Rx-OTC Indicator of 'O' or 'P'
Universal Product Code (UPC) and Health Related Item Code (HRI): (Product Type 1 (UPC) and Product Type 2 (HRI), unless on the covered drug list) (Except for diabetic test strips)	Product Type 1 (UPC) and Product Type 2 (HRI), unless on the covered drug list

Operational Table

Patent Cliff Strategy	Generic products of: Vagifem, Advair Diskus, Nuvaring, or products with the following reject message: "#NDC NOT COVERED, USE <BRAND DRUG>#"
Prescription Drugs with OTC Equivalents	Reject with message "OTC ALTERNATIVE AVAILABLE"
Category Lockout	A series: Non-sedating Antihistamines Included on FID 00311 and Tiers 74 and 77 F series: Non-sedating Antihistamines Included on FID 00310 and Tiers 74 and 77
Multi-Source Code (MSC) = 0 (Except for Alliant Health plan who considers MSC=0 a formulary exception. These products should NOT be excluded as a benefit exclusion for Alliant Health Plan)	
Products that reject with the following message (including the asterisks): "****Not A Covered Product or Service. Please Contact Prescriber****"	

Optional Coverage classes, Benefit Exclusion **UNLESS** covered. Refer to BET for details

Weight Loss Agents If client is LGHIB or SEIB, weight loss agents are always excluded for all indications and no BET check is necessary. If client is Alliant Health Plan, weight loss agents are always excluded for all indications and no BET check is necessary. All other clients: Weight Loss Agents for weight loss, (unless BET lists this category as covered)	Third Party Restriction Code 8
Infertility, (unless BET lists this category as covered)	Third Party Restriction Code 7
Sexual Dysfunction Agents, (unless BET lists this category as covered)	Third Party Restriction Code V (with the exception of Cialis 2.5 and 5 mg, as indicated for Benign Prostatic Hyperplasia). In addition, until such time as a third party restriction code of V is added to Addyi, that product will also be included in this group)
Compounds (unless BET lists this category as covered)	

POLICY REVIEW CYCLE

Effective Date	Date of Origin	Status
01-01-2026		Draft Pending