

POLICY NAME	Excluded Drug List	POLICY #	560P
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Criteria

Exclusion Criteria – Any of the following prevents coverage

- ☐ Non-prescription drugs [i.e., over-the-counter (OTC) medications] and devices, except for insulin, insulin syringes, or items required for coverage as part of Preventive Health and/or Women's Wellness Benefit (examples include aspirin, folic acid, etc.)
 - This includes non-sedating antihistamines available OTC (such as Claritin, Claritin-D etc.)
 - This includes prescription medications that have are available OTC (please note: the OTC drug does not have to be available in the same strengths or formulations)
- ☐ Weight loss medications (unless otherwise specified)
- ☐ Medications for cosmetic use (such as tretinoin, psoralens, etc.)
- ☐ Medications for hair loss or hair growth promoting agents
- ☐ Anabolic steroids
- ☐ Erectile dysfunction medications when used for lifestyle enhancement or performance when plan benefits do not include a lifestyle rider
- ☐ Products classified as Prescription Medical Devices by the FDA (such as support garments, mechanical pumps, test reagents, wound gels, hypodermic needles, etc.)
- ☐ Products classified as Medical Food or supplements (such as Deplin, Neocate, Pediasure, Ensure, etc.)
- ☐ Any drug labeled; "Caution—Limited by Federal Law to Investigational Use" or considered experimental, investigational or for research purposes
- ☐ Any drug prescribed for off-label or unapproved uses (excluding chemotherapy agents)
- ☐ Medications within the same pharmacologic class prescribed concurrently for the same indication that could be considered duplication of therapy
- ☐ Medical marijuana is excluded from coverage since it is classified by the federal government as a Schedule I controlled substance
- ☐ Drugs which have not been approved as effective by the FDA, including DESI drugs

Exclusion Criteria – Any of the following prevents coverage

- ☐ Medications used for treatment of decreased sexual desire (Addyi, Vyleesi) Statement of the Policy
- ☐ Prescription-strength benzoyl peroxide and combination products
- ☐ Dermatologic drugs (oral and topical) that have an existing covered generic formulation and offer no additional clinical benefit (such as Clobex lotion/shampoo (clobetasol), Vanos (fluocinonide), Capex, Luxiq (betamethasone), Olux (clobetasol or emulsion), Verdeso Aer (desonide foam), Solodyn (minocycline), etc.
- ☐ Vaccinations prescribed outside of the CDC supported recommendations (unless medically indicated)
 - This includes unapproved patient populations
- ☐ Formulations which are a combination of two or more existing drugs (prescription or OTC) which offer no additional clinical benefit compared to taking the individual components (please note: the existing drugs do not have to be commercially available in the same strengths as the combination product)
- ☐ Formulations of drugs (brand or generic) in which there is a commercially available alternate drug in which the non-preferred formulation offers no additional clinical value as demonstrated in peer review literature over the current existing therapies
- ☐ Compounded products such as:
 - Containing one or more ingredients that are bulk powders
 - Containing ingredients that are not FDA approved
 - Containing bioidentical hormones which are not considered standard of care treatment based on peer reviewed literature
 - Compounding kits with two or more commercially available drugs (prescription or over-the-counter) that offer no additional clinical benefit compared to taking the individual components
 - Prescribed for use or route not FDA approved or supported by clinical literature
- ☐ V-Go Insulin Delivery Device is excluded from coverage due to lack of sufficient evidence and conclusions on its safety and efficacy
- ☐ CeQur Simplicity Wearable Insulin Patch is excluded from coverage due to lack of established clinical benefits over covered alternatives
- ☐ Prescription digital therapeutics products are excluded from coverage because long term clinical efficacy has not been evaluated and established
- ☐ Ketamine IV will be excluded for coverage for all off-label uses, including analgesia, complex regional pain syndrome, unipolar disorder, bipolar depression, epilepsy, migraine headache, post-traumatic stress disorder, and nonmalignant pain

Services excluded from coverage:

- ☐ Items not filled at a Health Alliance participating pharmacy

- ☐ Outpatient prescription drugs for which the cost is recoverable under Worker's Compensation or Occupational Disease Law or any state of government agency, or hospice, or any medication furnished by another drug or medical service for which there is no charge to the member.
- ☐ Any charge for the administration of a drug.
- ☐ Any fill or replacement for medications that are lost, stolen, damaged, spilled, spoiled, etc.
- ☐ Prescriptions refilled before 75% of the previously dispensed 30-day supply should have been consumed when taken as prescribed.
- ☐ Prescriptions for ophthalmic products refilled before 70% of the previously dispensed 30-day supply should have been consumed.
- ☐ Any drug determined to be abused/misused or obtained through intentional misuse of the prescription drug benefit by a member.
- ☐ Drug costs exceeding the maximum default rate not otherwise approved
- ☐ Any drug or service obtained before becoming covered or after coverage has terminated
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DISCLAIMER This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-