

FEBRUARY 13, 2019



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PHARMACY AND THERAPEUTICS (P&T) COMMITTEE MEETING

NORTH CAROLINA STATE HEALTH PLAN
3200 ATLANTIC AVENUE, RALEIGH, NC 27604

Pharmacy and Therapeutics (P&T) Committee Meeting

Wednesday, February 13th 2019, 6:30 p.m. to 8:00 p.m.

Agenda

<u>Topic:</u>	<u>Presenter:</u>
<p>1. Welcome</p> <ul style="list-style-type: none"> • Call to Order • Roll Call 	<p>Carl Antolick III, Chair</p>
<p>2. Conflict of Interest Statement</p>	<p>Carl Antolick III, Chair</p>
<p>3. Old Business</p> <ul style="list-style-type: none"> • Formulary Development and Management at CVS Caremark • Minutes from August 21, 2018 Meeting* • Recent Plan Formulary Decisions 	<p>Carl Antolick III, Chair</p>
<p>4. Formulary Updates*</p> <ul style="list-style-type: none"> • Formulary Drug Exclusions • Tier Changes <ul style="list-style-type: none"> ○ Downtier ○ Uptier • Formulary Additions 	<p>Carl Antolick III, Chair</p> <p>Heather Renee Jarnigan, CVS</p> <p>Heather Renee Jarnigan, CVS</p> <p>Heather Renee Jarnigan, CVS</p>
<p>5. Utilization Management Policy Review*</p> <ul style="list-style-type: none"> • New Policies Under Consideration <ul style="list-style-type: none"> ○ Butalbital Containing Analgesics (Brand/Generics) Policy ○ Fortamet, Glumetza Policy (Proposed Revisions) ○ Onfi Policy ○ Orilissa Policy ○ Rheumatoid Arthritis Enhanced SGM 	<p>Carl Antolick III, Chair</p> <p>Stephanie Morrison, CVS</p>
<p>6. Adjourn</p> <ul style="list-style-type: none"> • Next Meeting: <i>Wednesday, May 15th 2019 from 6:30 to 8:00 PM via webinar</i> 	<p>Carl Antolick III, Chair</p>



STATE HEALTH PLAN FOR TEACHERS AND STATE EMPLOYEES

ETHICS AWARENESS & CONFLICT OF INTEREST REMINDER

(to be read by the Chair of the P&T Committee or his or her designee at the beginning of each meeting)

In accordance with the NC State Health Plan for Teachers and State Employees' ethics policy, it is the duty of every member of the Pharmacy and Therapeutics ^{Committee}, whether serving in a vote casting or advisory capacity, to avoid both conflicts of interest and appearances of conflict.

Does any Committee member have any known conflict of interest or the appearance of any conflict with respect to any manufacturers of any medication to be discussed at today's meeting?

Or, if during the course of the evaluation process if you identify a conflict of interest or the appearance of a conflict.

If so, please identify the conflict or appearance of conflict and refrain from any undue participation¹ in the particular matter involved.

¹ "A public servant shall take appropriate steps, under the particular circumstances and considering the type of proceeding involved, to remove himself or herself to the extent necessary, to protect the public interest and comply with this Chapter, from any proceeding in which the public servant's impartiality might reasonably be questioned due to the public servant's familial, personal, or financial relationship with a participant in the proceeding." *See N.C.G.S. §138A-36 (c). If necessary, the Chairman or individual member involved should consult with his ethics liaison, legal counsel, or the State Ethics Commission to help determine the appropriate response in a given situation. Rev. 1-16-07*



Formulary Development and Management at CVS Caremark®

Development and management of drug formularies is an integral component in the pharmacy benefit management (PBM) services CVS Caremark provides to health plans and plan sponsors. Formularies have two primary functions: 1) to help the PBM provide pharmacy care that is clinically sound and affordable for plans and their plan members; and 2) to help manage drug spend through the appropriate selection and use of drug therapy.

Underlying principles of the CVS Caremark Formulary Development and Management Process include the following:

- CVS Caremark is committed to providing a clinically appropriate formulary.
- Decisions on formulary are made by a committee of independent, unaffiliated clinical pharmacists and physicians.
- The physician always makes the ultimate prescribing determination as to the most appropriate course of therapy.

The CVS Caremark formulary development process is based on nearly two decades of experience as well as extensive clinical pharmaceutical management resources. The formulary is developed and managed through the activities of the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee (“P&T Committee”) and Formulary Review Committee (FRC).

CVS Caremark National Pharmacy and Therapeutics Committee

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. Two physicians and two pharmacists are experts in the care of the elderly or disabled. One of the physicians is a medical ethicist. The role of the medical ethicist is to assist in the decision-making process by facilitating the discussion, as needed, and to provide unbiased feedback with respect to the logic and appropriateness of the conclusions drawn and the decisions reached. The composition of the P&T Committee exceeds the Centers for Medicare and Medicaid Services (CMS) P&T Committee requirements for Medicare Part D sponsors and also exceeds URAC standards.

CVS Caremark National Pharmacy and Therapeutics Committee Membership		
4 pharmacists, including	18 physicians, representing	
1 academic pharmacist	Allergy	Internal medicine
1 hospital pharmacist	Cardiology	Infectious disease
2 geriatric pharmacists	Clinical pharmacology	Pediatrics
	Endocrinology	Neurology
	Family practice	Medical ethics
	Gastroenterology	Pharmacoeconomics
	Gerontology	Pharmacology
	Hematology/oncology	Psychiatry-adult/ pediatric/adolescent
		Rheumatology

1. All drugs that are legally marketed under the Federal Food Drug and Cosmetic Act (e.g., “grandfathered” drugs).

The regular voting members on the P&T Committee are not employees of CVS Caremark. The P&T Committee is charged with reviewing all drugs, including generics that are represented on the CVS Caremark approved drug lists. The approvals made are non-biased, quality driven and evidence based. The clinical merit of the drug, not the cost, is the primary consideration of the P&T Committee.

New members are included on the current P&T Committee on the basis of active involvement in clinical practice (patient care), whether in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees. The P&T Committee members are compensated for their participation with an appropriate honorarium and any travel/hotel expenses incurred in the process of serving on the P&T Committee.

The P&T Committee meets face-to-face on a quarterly basis and, as needed, on an ad hoc basis. CVS Caremark has a stringent conflict of interest policy for P&T Committee members. CVS Caremark requires each P&T Committee member to complete a Conflict of Interest Disclosure Statement annually. Completed Conflict of Interest Statements are carefully scrutinized by the CVS Caremark Chief Health Officer and Vice President of Clinical Affairs responsible for formulary development and maintenance. An objective party in the CVS Caremark Compliance Department verifies that conflict of interest requirements have been met. Through this careful review, CVS Caremark helps ensure that the P&T Committee meets or exceeds all federal and state regulatory requirements for conflict of interest, including CMS, and all industry accreditation standards, including URAC and the National Committee for Quality Assurance (NCQA).

Clinical Formulary Department

The P&T Committee functions are supported by the CVS Caremark Clinical Formulary Department. Clinical pharmacists in the Formulary Department prepare individual Drug Monographs and Therapeutic Class Reviews following a comprehensive review of available clinical literature. Numerous references and information resources are used to assist in the evaluation and review of the medications under consideration for formulary addition. These peer-reviewed resources are selected based on being accurate, reliable, current, comprehensive and well-respected.

Formulary Development and Maintenance Process

The P&T Committee bases decisions on scientific evidence, standards of practice, peer-reviewed medical literature, accepted clinical practice guidelines and other appropriate information. The P&T Committee reviews medications from a purely clinical perspective; it does not have access to nor does it consider any information on rebates, negotiated discounts or net costs. In alignment with this clinical perspective, the P&T Committee also reviews new drug evaluations, new U.S. Food and Drug Administration (FDA)-approved indications, new clinical line extensions and publications on new clinical practice trends.

In evaluating new drugs for formulary inclusion, the P&T Committee reviews the individual drug monographs, pivotal clinical trials accompanying the drug monographs, and therapeutic class reviews prepared by the Clinical Formulary Department. P&T Committee members share insights based on their clinical practice and the quality of published literature. FDA-approved drug products¹ are reviewed and considered for inclusion on the Formulary and standard formularies/drug lists by the P&T Committee. The P&T Committee also reviews and approves all utilization management (UM) criteria (i.e., prior authorization, step therapy and quantity limits outside of FDA-approved labeling).

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. In addition, the P&T Committee reviews all UM criteria annually.

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Review of new drugs or new indications for drugs in six classes is expedited. These classes include the immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals and antineoplastics. For drugs in these classes, the P&T Committee makes a National Formulary and Medicare Part D Drug List status decision within 90 days of launch/market availability. For drugs outside of these classes, the P&T Committee makes a National Formulary decision within 90 days of launch/market availability and a Medicare Part D Drug List status decision within 180 days of launch/market availability. In addition, the P&T Committee will make formulary status decisions for the Managed Medicaid Drug List and Health Exchanges Formularies within 90 days of launch/market availability of newly FDA-approved drugs, or will provide a clinical justification if this timeframe is not met.

Formulary Review Committee

The FRC is an internal CVS Caremark committee that evaluates additional factors that may affect the formulary. For example, when two or more drugs produce similar clinical results, the FRC may evaluate factors such as:

- Utilization trends
- Impact of generic drugs or drugs designated to become available over-the-counter
- Brand and generic pipeline
- Line of business
- Plan sponsor cost
- Applicable manufacturer agreement
- 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.

Formulary Management

The formulary is a dynamic tool that may be responsive to changes in the marketplace. It is intended to offer savings to clients while ensuring clinically appropriate products are available for members to use. Clients may choose to utilize CVS Caremark formularies for their plans or use them as the foundation for custom formularies.

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. The generic and low-cost brand-name options offer similar efficacy and safety. Since many brand-name drugs do not provide clear clinical and/or financial advantages when compared to available drug options within the therapeutic class, several strategies are available to promote cost-effective use of medications ranging from tiered copayments, excluding products from coverage or having a closed plan design.

- Tiered copayments encourage members to use preferred formulary drugs. A three-tier formulary—typically with generics in the first, lowest cost tier; preferred brand-name drugs at second tier; and non-preferred brand-name drugs at the highest-cost third tier—is the option chosen by the vast majority of plan sponsors working with CVS Caremark.
- Many of our standard formularies also exclude certain products from coverage. The excluded products have alternatives available that will deliver cost savings to plan sponsors.
- Closed formularies will cover a set number of products and the others are not covered unless the claim goes through an override process.

1. All drugs that are legally marketed under the Federal Food Drug and Cosmetic Act (e.g., “grandfathered” drugs).

Within these plan designs, clients may opt to implement a formulary exception process where members, after meeting certain criteria, could have an excluded product covered, or could receive a third-tier product at a second-tier copay.

All formularies include generic drugs, and generics are typically in the lowest tier of pricing for members. Brand-name products may be considered preferred or non-preferred in the common three-tier plan design. Preferred brand-name drugs are encouraged with a lower copay than non-preferred brand-name products.

Formulary Compliance

Plan design, as noted above, is primary in achieving formulary compliance. CVS Caremark also provides plan sponsors with a range of solutions that encourage the use of generics and preferred brand-name drugs. Many CVS Caremark clients choose a plan that requires that a cost-effective generic be used before a single-source brand in the same therapeutic class.

Promotion of generics. When an A-rated generic becomes available, it is considered preferred and proactively encouraged. At that point, significant efforts are made to transition utilization to the lower-cost generic product. Client plan design will direct the effort and can be very aggressive and only cover the generic, or be more moderate and require the member to pay the difference between the brand-name drug and the generic if the brand-name product is chosen. Some clients may no longer cover the brand-name drug if a generic is available.

Member-directed formulary education. Members are notified when a new brand-name or generic product replaces a product they are using on the formulary. They are also notified if a product they are using is removed from the drug list, which could occur due to withdrawal from the market for safety reasons. If a non-preferred product has been dispensed at a retail pharmacy due to a prescription marked "Dispense as Written," the member may also be alerted about alternative formulary product(s) that could be available at a lower copayment.

The website, Caremark.com, in addition to providing a simple way to order prescription refills, allows the member to access information about their specific drug list, pricing information and generic availability, as well as general drug and health information.

Improving Member Experience and Outcomes

CVS Caremark is focused on helping members achieve their health and wellness goals through proper understanding and utilization of their medications. There are a number of strategies used to support members in their desire for positive outcomes including:

- Helping them become knowledgeable about their plan, benefit structure and drug therapy management options
- Helping them understand and comply with their prescribed therapies by providing:
 - Adherence counseling with all new prescriptions (face-to-face at CVS Pharmacy® locations, by letter through mail service and retail network)
 - Refill reminders (letters, Interactive Voice Response [IVR], Internet) and non-adherent prompts (letters and phone calls)
 - Availability of automatic prescription renewals and refills
 - Information about ways to save on prescriptions by using lower-cost alternatives or lower-cost channels
- Coordinating with plan sponsors to promote enrollment in wellness and health management programs and offering appropriate and timely immunizations
- Making formularies readily available on Caremark.com

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PHARMACY AND THERAPEUTICS (P&T) COMMITTEE

October 23, 2018

The meeting of the Pharmacy and Therapeutics (P&T) Committee of the North Carolina State Health Plan for Teachers and State Employees (The Plan) was called to order at 6:30 P.M. (EST) on Tuesday, October 23, 2018, via webinar, accessible to the public through the Plan's website. Quorum was present.

MEMBERS PRESENT:

Sundhar Ramalingam, MD, Oncologist, Duke Cancer Center
Peter Robie, MD, General Internist, Wake Forest Baptist Community Physicians
Tony Gurley, RPh, JD, Owner/Pharmacy Manager, Glenwood South Pharmacy + Market
David Konanc, MD, Neurologist, Raleigh Neurology Associates
John Anderson, MD, MPH, Chief Medical Officer, Duke Primary Care

MEMBERS ABSENT:

John J. Engemann, MD, Infectious Disease Specialist, Raleigh Infectious Disease Associates, PA
Joseph Shanahan, MD, Owner, Shanahan Rheumatology & Immunotherapy
Matthew K. Flynn, MD, Founder, Family Dermatology
Jennifer Burch, PharmD, Owner, Central Compounding Center

PLAN & VENDOR STAFF:

Carl Antolick III, PharmD, Clinical Pharmacist (Chair), State Health Plan
Tracy Linton, MPH, Sr. Director, Plan Benefits, State Health Plan
Neha Zadoo, Pharmacy Business Analyst, State Health Plan
Natasha Davis, Pharmacy Benefits Program Manager, State Health Plan
Dee Jones, Executive Director, State Health Plan
Renee Jarnigan, RPh, Clinical Advisor, CVS Health
Stephanie R. Morrison, PharmD, BCPS, Clinical Advisor, CVS Health

Welcome:

The Chairperson welcomed the Committee members and guests to the webinar and performed roll call.

Conflict of Interest

In compliance with the requirements of Chapter 138A-15(e) of the State Government Ethics Act the Chairperson read the NCSHP's Ethics Awareness & Conflict of Interest Reminder to the P&T Committee members and requested that members who have either an actual or perceived conflict of interest identify the conflict and refrain from discussion and voting in those matters as appropriate. No conflicts of interest were noted.

Old Business:

The Chairperson summarized some of the Plan's recent formulary decisions. This includes removing the following products from the formulary: LAZANDA, ZOLPIMIST, levorphanol, fluocinonide 0.1% cream hydrocortisone 1% in Absorbase, & benzonatate 150 mg capsules; moving the following branded products to non-preferred status: BENZACLIN, MIRAPREX, MINASTRIN 24 FE chewables, APTENSIO

XR, & QUILLIVANT XR; and adopting the following new utilization management criteria: Nuedexta Initial Prior Authorization, Topical NSAIDs Initial Prior Authorization with Quantity Limit, Chenodal Initial Prior Authorization, Naprelan Initial Prior Authorization, & Thiola Initial Prior Authorization. All of these changes were approved by the Committee during May's meeting and subsequently went into effect October, 1 2018.

Minutes from Previous P&T Meeting:

The Chairperson asked the P&T Committee members to review the August 2018 P&T meeting minutes, which were distributed prior to the meeting. There were no additions or corrections to the minutes so they were approved as is.

Formulary Updates:

The Chairperson explained that CVS Caremark had announced their 2019 formulary strategy on August 1, 2018 which will include the removal of 23 drugs from the formulary and the adding back of 4 drugs. On October 1, 2018 the full drug list was released to the public and would be reviewed in full during the meeting. The Chairperson made note that the One Touch products would not be removed from the Plan's formulary and replace with the Accu-chek product line due to limited return on investment compared to the anticipated member disruption.

Next, CVS Caremark Clinical Advisors Heather Renee Jarnigan, RPh, & Stephanie Morrison, PharmD, BCPS presented CVS Caremark's Quarterly Formulary Updates which will be effective January 1, 2019. This included drug removals and additions to the formulary as well as tier changes and utilization management policies. Ms. Jarnigan reviewed the following products that will be excluded from the formulary starting 2019: Contrave, Jentaduetto, Jentaduetto XR, Tradjenta, Acanya, Benzacilin, Onexton, Veltin, Ziana, Cambia, Sorilux, Acticlate, Targadox, Zuplenz, Vanatol LQ, Tirosint, Avenova, Cimzia, Lupron Depot Kit 7.5, 22.5, 30, & 45 MG, Elocate, Alprolix, Zemaira, Fasentra & chlorzoxazone 250 MG. All products being removed have comparable preferred generic formulary options available as alternative therapies. During the discussions it was explained that there is an exceptions process available for any excluded product if deemed medically necessary. Also, it was suggested by Dr. Anderson that maybe butalbital products should also be excluded from the formulary due to their lack of efficacy in treating migraines. The Plan will analyze possible exclusion as well as consider more stringent quantity limits. There was no opposition to the formulary removals from the Committee members so the changes were approved as presented.

Ms. Jarnigan identified all of the branded products that will be moving to a non-preferred status, or uptiered. They include: Fentora, Welchol, Pyridium, Lupron Depot Kit 3.75 & 11.25 MG, & Zoladex. All of these products have formulary alternatives that are preferred. There was no opposition from the Committee members so the changes were approved as presented.

Ms. Jarnigan identified all of the branded products that will be moving to a preferred status, or duntiered. They include: Arnuity Ellipta, Abstral, Eucrisa, Zejula, Aralast NP, Glassia, Nucala, & Prolastin-C. There was no opposition from the Committee members so the changes were approved as presented.

Ms. Jarnigan identified all of the medications that were being removed from CVS's New-to-Market block and would be available as covered products effective October 1, 2018, while Dr. Morrison covered any utilization management policies that went along with the new products. The new medications being added to the formulary are as follows: Adynovate, Ajoyv, Aliqopa, Alunbrig, Azedra, Bortexamib, Braftovi, Bromsite, Bupivacaine, Butalbital/APAP 50-300 mg, Durolane, Embeda, Emgality, Epinephrine, Erleada, Glyxambi, Idelvion, Jivi, KCL/D5W 20-250 mL, Kyprolis, Lenvima 4/12 mg, Mektovi, Nerlynx, Novarel, Nuplazid, Orkambi, Pancreaze, Phenylephrine, Poteligeo, Rebinyn, Rhopressa, Sernivo, Signifor LAR 10/30 mg, Siklos, Tibsovo, Ultravate, Vancomycin, Vyxeos, Vyzulta, Xeljanz, Xeljanz XR & Zemdri. There was no opposition from the Committee members so the additions were approved as presented.

The Committee then reviewed new utilization management policies that were under consideration for adoption. They included: Corticosteroid-Pulmicort 1 MG Post Limit Prior Authorization & Select Medical Devices Initial Prior Authorization. There was no opposition from the Committee members so the new policies would be enacted on January 1, 2019.

Adjourn

Dr. Antolick addressed the Committee by thanking them for their service and informed them that the Plan still has to determine the 2019 meeting dates. The meeting was adjourned at approximately 8:30 P.M. (EST).



Carl Antolick III, Chair

RECENT PLAN FORMULARY DECISIONS (Effective January 1, 2019)

1. EXCLUSIONS

- a. The following products are removed from the Formulary due to price or rebate increases, to reduce year over year pharmacy spend.
- b. There are other more cost-effective alternatives on the formulary.
- c. Drugs Affected:
 - i. ACANYA, BENZACLIN, ONEXTON, VELTIN, ZIANA, JENTADUETO, JENTADUETO XR, TRADJENTA, CAMBIA, CONTRAVE, SORILUX, ACTICLATE, TARGADOX, ZUPLLENZ, VANATOL LQ, TIROSINT, AVENOVA, ZEMAIRA, ELOCTATE, LUPRON DEPOT, FASENRA, ALPROLIX, & CIMZIA.

2. UPTIERS

- a. Movement of a drug from preferred status to non-preferred status
- b. Mostly multi-sourced branded drugs with available generics or other preferred options
- c. Drugs Affected:
 - i. LUPRON DEPOT KIT 3.75MG AND 11.25MG, ZOLADEX, FENTORA, WELCHOL PAK 3.75GM, & PYRIDIDIUM tablet 100MG.

3. DOWNTIERS

- a. Movement of a drug from non-preferred status to preferred status
- b. Mostly single-sourced branded drugs without available generics
- c. Drugs Affected:
 - i. ARALAST NP, GLASSIA, ZEJULA CAP, NUCALA, ARNUITY ELLIPTA, ABSTRAL, PROLASTIN-C & EUCRISA.

4. ADDITIONS

- a. Additions of new drugs or new formulations to the formulary
- b. Typically drugs that have been released to the market recently, but up to one year
- c. May have been previously on block by CVS Caremark and are now being added to the formulary.
- d. Drug Affected:
 - i. ERLEADA, ADYNOVATE, JIVI, DUROLANE, RHOPRESSA, IDELVION, XELJANZ, XELJANZ XR, REBINYN, EMBEDA, GLYXAMBI, VYZULTA, SERNIVO, & ULTRAVATE lotion 0.05%.

Therapeutic Category/ Subcategory	Brand Name	Generic Name	Specialty Flag	Rationale/Alternatives	Change Type	CVS Change	Proposed NC Status/Tier	# Utilizers (6 mo)
Topical/ Dermatology/ Corticosteroids/ High Potency	TOPICORT	Desoximetasone Topical	N	Availability of other medium potency corticosteroids for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Topicort cream formulations are already on formulary as non-preferred (tier 3). Preferred options include betamethasone valerate cream, lotion, ointment 0.1%; clocortolone cream 0.1%; desoximetasone cream, ointment 0.05%; fluocinolone acetonide cream, ointment 0.025%; fluticasone propionate cream, lotion 0.05%, ointment 0.005%; hydrocortisone butyrate cream, ointment, solution 0.1%; hydrocortisone valerate cream, ointment 0.2%; mometasone cream, lotion, ointment 0.1%, triamcinolone acetonide cream, lotion 0.025%; triamcinolone acetonide cream, lotion, ointment 0.1%; Cutivate (fluticasone propionate cream, lotion 0.05%, ointment 0.005%), and Elocon (mometasone cream, lotion, ointment 0.1%).	Negative Tiering Change	2--> 3	3	0
Central Nervous System/ Multiple Sclerosis Agents	COPAXONE SYN 20MG/ML	Glatiramer Acetate Injection	Y	To provide an additional option for the treatment of multiple sclerosis.	Positive Tiering Change	3 -> 2	5	n/a
Hematologic/ Thrombocytopenia Agents	MULPLETA TAB 3MG	Lusutrombopag Oral	Y	To provide an option for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.	Positive Tiering Change	Tier 3/ ACSF--> Tier 2/ ACSF	5	n/a
Respiratory/ Severe Asthma Agents	DUPIXENT SOL	Dupilumab Injection	Y	To provide an additional option for the treatment of moderate-to-severe asthma.	Positive Tiering Change	Tier 3/ ACSF--> Tier 2/ ACSF	5	n/a
Central Nervous System/ Antipsychotics/ Atypicals	ARISTADA INJ INITIO	Aripiprazole Lauroxil Injection	N	Line extension. To provide an option for the a loading dose initiation of Aristada when used for the treatment of schizophrenia in adults.	Positive Tiering Change	3--> 2	2	0

Therapeutic Category/ Subcategory	Brand Name	Generic Name	Specialty Flag	GPI	CVS Block Removal Date	Proposed NCSHP Tier	Comments	UM Status	New Molecular Entity
Anti-Infectives/ Antibacterials/ Tetracyclines	XERAVA INJ 50MG	Eravacycline Injection	N	04300030102120	10/17/2018	3	Tetracycline antibiotic for complicated IA infection; New-To-Market GPI. Term blocked from coverage status.	No UM	Y
Anti-Infectives/ Antibacterials/ Aminoglycosides	ARIKAYCE SUS	Amikacin Oral Inhalation	Y	07000010121830	10/24/18	6	Oral Amikacin; Not included on 2549 on 10-17-18; confirmed on Specialty Drug List Universe from 10-16-18	No UM	Y
Antineoplastics and Adjunctive Therapies/Antineoplastic - Antibodies	LUMOXITI SOL 1MG	Moxetumomab Pasudotox-tdfk Injection	Y	21353036502120	11/8/2018	6	A CD22-directed cytotoxin indicated for the treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies	SGM	Y
Antineoplastic Agents/ Monoclonal Antibodies	LIBTAYO INJ 350/7ML	Cemiplimab-rwlc Injection	Y	21353023402030	11/14/2018	6	PD-1 antibody indicated for tx of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for surgery or radiation.	SGM	Y
Central Nervous System/ Polyneuropathy	ONPATTRO SOL 10MG/5ML	Patisiran Injection	Y	62706060102020	11/14/2018	6	siRNA indicated for tx of the polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adults.	SGM	Y
Central Nervous System/ Anticonvulsants	EPIDIOLEX SOL 100MG/ML	Cannabidiol Oral	Y	72600017002020	12/1/2018	6	Cannabidiol indicated for tx of seizures associated with Lennox-Gastaut or Dravet Syndrome	SGM	Y
Topical/ Ophthalmic/ Miscellaneous	OXERVATE SOL 20MCG/ML	Cenegermin-bkbj Ophthalmic	Y	86770020202020	12/19/2018	6	Ophthalmic recombinant human nerve growth factor indicated for tx of neurotrophic keratitis	No UM	Y
Anti-Infectives/ Antiretroviral Agents/ Antiretroviral Combinations	JULUCA TAB 50-25MG	Dolutegravir Sodium/Rilpivirine Hydrochloride Oral	Y	12109902280320	12/19/2018	3	Combo INSTI and NNRTI indic for tx of HIV-1 in adults; Specialty but takes oral HIV tier 3 instead of 6	No UM	Y
Antineoplastic Agents/ Kinase Inhibitors	LORBRENA TAB 25MG, 100MG	Lorlatinib Oral	Y	21534056000320, 21534056000330	12/19/2018	6	Kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)	SGM	Y
Endocrine and Metabolic/ Metabolic Modifiers/ Fabry Disease	GALAFOLD CAP 123MG	Migalastat Hydrochloride Oral	Y	30903650100120	12/19/2018	6	Tx of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant	SGM	Y
Hematologic/ Thrombocytopenia Agents	MULPLETA TAB 3MG	Lusutrombopag Oral	Y	82405045000320	1/2/2019	5	Tx of thrombocytopenia in adults w/ chronic liver dz who are scheduled for a procedure	Spec QL only	Y
Antineoplastic Agents/ Kinase Inhibitors	VITRAKVI CAP 25MG, 100MG, 20MG/ML	Larotrectinib Oral	Y	21533835200120, 21533835200150, 21533835202020	1/2/2019	6	Tx of solid tumors with a NRTK gene fusion (in adult & peds)	SGM	Y
Anti-Infectives/ Micellaneous	NUZYRA INJ 100MG, TAB 150MG	Omadacycline Injection & Oral	N	04200050202120, 04200050200320	1/2/2019	3	TCN antibiotic for CAP and ABSSSI	No UM	Y

Therapeutic Category/ Subcategory	Brand Name	Generic Name	Specialty Flag	GPI	CVS Block Removal Date	Proposed NCSHP Tier	Comments	UM Status	New Molecular Entity
Endocrine and Metabolic/ Miscellaneous	REVCIVI INJ 1.6MG/ML	Elapegademase-lvlr Injection	Y	30902030202020	1/2/2019	6	Elapegademase-lvlr is an exogenous source of adenosine deaminase enzyme that reduces levels of toxic adenosine and deoxyadenosine and increases lymphocytes. Adenosine deaminase is the enzyme that catalyzes the deamination of both adenosine and deoxyadenosine. Lack of adenosine deaminase activity results in severe immunodeficiency disease (often fatal).	No UM	Y
Anti-Infectives/ Miscellaneous	AEMCOLO TAB 194MG	Rifamycin Sodium Oral	N	16000048200620	2/9/2019	3	Rifamycin indicated for traveler's diarrhea	No UM	Y
Immunosuppressive Agents/ Monoclonal Antibodies	GAMIFANT INJ 10MG/2ML, 50/10ML	Emapalumab-lzsg Injection	Y	99405035402020, 99405035402040	1/18/19	6	Tx of pts with primary hemophagocytic lymphohistiocytosis (HLH) w/ refractory, recurr or progressive dz or intolerance to conventional HLH therapy.	No SGM	Y
Central Nervous System/ Potassium-Channel Blocker	FIRDAPSE TAB 10MG	Amifampridine Oral	Y	76000012100320	1/18/19	6	Tx of Lambert-Eaton myasthenic syndrome (LEMS)	No SGM	Y
Endocrine and Metabolic/ Detoxification Agents	ANDEXXA SOL 200MG	Andexanet Alfa Injection	N	93000014402130	1/24/19	3	Recombinant Factor Xa - antidote for apixaban or rivaroxaban	No UM	Y
Endocrine and Metabolic/ Potassium-Removing Agents	LOKELMA PAK 5GM, 10GM	Sodium Zirconium Cyclosilicate Oral	N	99450020003020, 99450020003040	12/7/2018	2	Oral potassium binder indicated for the treatment of hyperkalemia in adults.	No UM	Y
Endocrine and Metabolic/ Endometriosis	ORILISSA TAB 150MG, 200MG	Elagolix Oral	N	30090030100320, 30090030100330	12/7/2018	2	GnRH receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis.		Y
Vaginal Products/Miscellaneous	INTRAROSA SUP 6.5MG	Prasterone Vaginal	N	55400055009920	10/11/2017	3	Steroid DHEA (prasterone) indicated to tx mod to severe dyspareunia due to menopause.	No UM	Y

Therapeutic Category/ Subcategory	Brand Name	Generic Name	Specialty Flag	GPI	CVS Block Removal Date	Proposed NCSHP Tier	Comments	UM Status	UM Criteria	New Molecular Entity
Analgesics/ Opioid Analgesics	DVORAH TAB	Acetaminophen/Caffeine/ Dihydrocodeine Bitartrate Oral	N	65991303050320	1/2/2019	1	Acet-Caff-Dihydrocodeine 325-30-16 mg combination Tab	Opioid UM	Active	N
Anti-Infectives/ Antibacterials/ Miscellaneous	VANCOMYCIN INJ 750MG/7.5ML, 1000MG/10ML, 1250MG/12.5ML, 1500MG/15ML, 1750MG/17.5ML, 2000MG/20ML		N	16280080102050, 16280080102055, 16280080102060, 16280080102065, 16280080102070, 16280080102075	10/31/2018	3	New SSB	No UM	n/a	N
Anti-Infectives/ Antibacterials/ Miscellaneous	VANCOMYCIN SOL 1.5GM, 1.25GM		N	16280080102122, 16280080102121	1/2/2019	3	New SSB	No UM	n/a	N
Anti-Infectives/ Antibacterials/ Miscellaneous	VANCOMYC/D5W INJ 1.5/300		N	16280080122062	1/2/2019	3	New SSB	No UM	n/a	N
Antineoplastic Agents/ Kinase Inhibitors	KISQALI TAB 400DOSE, 600DOSE	Ribociclib Oral	Y	21531070500320, 21531070500320	1/24/19	5	Additional NDCs based on packaging	SGM	Active	N
Antineoplastic Agents/ Miscellaneous	SIKLOS TAB 1000MG	Hydroxyurea Oral	N	82803030000340	11/21/2018	3	New strength	No UM	n/a	N
Cardiovascular/ Calcium Channel Blockers	DILTIAZEM INJ 25MG/5ML		N	3400001010E520	12/26/2018	3	SSB - Prefilled Syringe Form	No UM	n/a	N
Central Nervous System/ Migraine/ Monoclonal Antibodies	EMGALITY INJ 120MG/ML	Galcanezumab-gnlm Injection	N	6770203530E520	1/24/19	2	Prefilled syringe; Pen formulation already on formulary	ST	Active	N
Endocrine and Metabolic/ Antidiabetics/ Insulins	TRESIBA INJ 100UNIT	Insulin Degludec Injection	N	27104007002020	1/18/19	2	Vial formulation; Flex Pen forms are already on formulary at Tier 2			N
Endocrine and Metabolic/ Antidiabetics/ Insulins	DIVIGEL GEL 0.75MG	Estradiol Transdermal	N	24000035004042	1/18/19	2	New strength (estradiol transdermal)		n/a	N
Hematologic/ Hematopoietic Agents	PROMACTA POW 12.5MG	Eltrombopag Olamine Oral	Y	82405030103030	1/24/19	6	Additional NDCs	SGM	Active	N
Hematologic/Anticoagulants	XARELTO TAB 2.5MG	Rivaroxaban Oral	N	83370060000310	11/8/2018	2	New strength	No UM	n/a	N
Immunologic Agents/ Immune Globulins	HIZENTRA INJ 1GM/5ML, 2GM/10ML, 4GM/20ML, 10/50ML	Immune Globulin Injection	Y	19100020202050, 19100020202054, 19100020202058, 19100020202065	12/19/2018	5	Formulations already on formulary at Tier 5 per NCSHP request of initial formulary customizations	SGM	Active	N
Immunologic Agents/ Immune Globulins	CYTOGAM INJ	Cytomegalovirus Immune Globulin Intravenous (Human) (CMV-IGIV) Injection	Y	19100005002200	12/19/2018	6	Immune globulin indicated for cytomegalovirus prophylaxis.	No UM	n/a	N

Therapeutic Category/ Subcategory	Brand Name	Generic Name	Specialty Flag	GPI	CVS Block Removal Date	Proposed NCSHP Tier	Comments	UM Status	UM Criteria	New Molecular Entity
Immunologic Agents/ Immunosuppressants	ZORTRESS TAB 1MG	Everolimus Oral	Y	99404035000335	11/14/2018	2	New strength	No UM	n/a	N
Immunologic Agents/ Miscellaneous	ANAVIP INJ	Crotalidae Immune F(ab') ₂ , Equine Origin Injection	N	19200022002120	12/19/2018	6	Antivenin mgmt indic for rattlesnake bites	No UM	n/a	N
Nutritional/Supplements/ Dietary Management Products	TYLACTIN POW BLD 20PE	formulation of glycomacropeptide and essential amino acids without added tyrosine and phenylalanine	N	81200000003000		3	Supplement for tx of tyrosinemia -- whole protein (glycomacropeptide or GMP); modified formulation of Glytactin (for tx of PKU),	No UM	n/a	N
Nutritional/Supplements/ Nutritional Therapy	AMINO ACID INJ 48MG/ML		N	80302010102010	11/21/2018	3	SSB Amino acid 5% infusion	No UM	n/a	N
Nutritional/Supplements/Electrolyte s	SODIUM BICARBONATE SOL 8.4%		N	79050020002026	11/8/2018	3	SSB Sodium Bicarb Inj	No UM	n/a	N
Respiratory/ Severe Asthma Agents	XOLAIR INJ 75MG/0.5ML, 150MG/ML	Omalizumab Injection	Y	4460306000E510, 4460306000E520	11/21/2018	6	Line extension	SGM	Active	N
Respiratory/ Severe Asthma Agents	DUPIXENT SOL	Dupilumab Injection	Y	4460352000E530	1/2/2019	5	New strength for asthma indication	SGM	Active	N
Hematologic/ Hematopoietic Growth Factors	RETACRIT INJ 2000UNIT, 3000UNIT, 4000UNIT, 10000UNT, 40000UNT	Epoetin Alfa Recombinant (Erythropoietin; EPO) Injection	Y	82401020042010, 82401020042015, 82401020042020, 82401020042040, 82401020042060	4/1/2019	4	Biosimilar - Epogen/Procrit	No UM	n/a	N

Utilization Management Policies

<i>Policy Name</i>	<i>Policy Type</i>
<i>Butalbital Containing Analgesics (Brand & Generic)</i>	Quantity Limits
<i>Fortamet, Glumetza Policy</i>	Initial Prior Authorization, Proposed Revisions
<i>Onfi Policy</i>	Initial Prior Authorization
<i>Orilissa Policy</i>	Quantity Limits
<i>Rheumatoid Arthritis Enhanced SGM</i>	Specialty Guideline Management

QUARTERLY FORMULARY UPDATES (Effective April 1, 2019)

1. EXCLUSIONS

- a. The following products are removed from the Formulary due to price or rebate increases, to reduce year over year pharmacy spend.
- b. There are other more cost-effective alternatives on the formulary.
- c. Drugs Affected:
 - i. ZYTIGA, EPOGEN, & PROCRIT.
 - ii. BUTALBITAL/ACETAMINOPHEN 50-300 MG, & DICLOFENAC GEL 1%.

2. UPTIERS

- a. Movement of a drug from preferred status to non-preferred status
- b. Mostly multi-sourced branded drugs with available generics or other preferred options
- c. Drugs Affected:
 - i. ATRALIN GEL 0.05%, COREG CR, ESTRACE VAGINAL CREAM 0.01%, LUZU CREAM 1%, UCERIS, MESTINON TIMESPAN, & TOPICORT.

3. DOWNTIERS

- a. Movement of a drug from non-preferred status to preferred status
- b. Mostly single-sourced branded drugs without available generics
- c. Drugs Affected:
 - i. COPAXONE SYRINGES 20MG/ML, MULPLETA TABLETS 3MG, DUPIXENT, & ARISTADA INITIO.

4. ADDITIONS

- a. Additions of new drugs or new formulations to the formulary
- b. Typically drugs that have been released to the market recently, but up to one year
- c. May have been previously on block by CVS Caremark and are now being added to the formulary.
- d. Drug Affected:
 - i. XERAVA, ARIKAYCE, LUMOXITI, LIBTAYO, ONPATTRO, EPIDIOLEX, OXERVATE, JULUCA, LORBRENA, GALAFOLD, MULPLETA, VITRAKVI, NUZYRA, REVCovi, AEMCOLO, GAMIFANT, FIRDAPSE, ANDEXXA, LOKELMA, ORILISSA, & INTRAROSA.
 - ii. DVORAH, VANCOMYCIN, KISQALI, SIKLOS, DILTIAZEM, EMGALITY, TRESIBA, DIVIGEL, PROMACTA, XARELTO, HIZENTRA, CYTOGAM, ZORTRESS, ANAVIP, TYLACTIN, AMINO ACID, SODIUM BICARBONATE, XOLAIR, DUPIXENT, & RETACRIT.

QUANTITY LIMIT CRITERIA

DRUG CLASS	BUTALBITAL CONTAINING ANALGESICS (BRAND AND GENERIC)
BRAND NAME (generic)	<p>(butalbital and acetaminophen)</p> <p>(butalbital, acetaminophen, and caffeine)</p> <p>(butalbital, acetaminophen, caffeine, and codeine)</p> <p>(butalbital, aspirin, and caffeine)</p> <p>(butalbital, aspirin, caffeine, and codeine)</p>
<i>Status: CVS Caremark Criteria</i>	
<i>Type: Quantity Limit</i>	

POLICY

FDA-APPROVED INDICATIONS

Butalbital containing products (e.g., Allzital, Esgic, Fioricet, Fioricet with Codeine, Fiorinal, Fiorinal with Codeine, Vanatol) are indicated for the relief of the symptom complex of tension (or muscle contraction) headache.

Evidence supporting the efficacy and safety of this combination product in the treatment of multiple recurrent headaches is unavailable. Caution in this regard is required because butalbital is habit-forming and potentially abusable.

LIMIT CRITERIA

This quantity limit should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

Drug	1 Month Limit*	3 Month Limit*
butalbital, acetaminophen, and caffeine solution	720 mL / 25 days	2160 mL / 75 days
butalbital 25 mg and acetaminophen 325 mg	96 units / 25 days	288 units / 75 days
butalbital and acetaminophen	48 units / 25 days	144 units / 75 days
butalbital, acetaminophen, and caffeine	48 units / 25 days	144 units / 75 days
butalbital, acetaminophen, caffeine, and codeine	48 units / 25 days	144 units / 75 days
butalbital, aspirin, and caffeine	48 units / 25 days	144 units / 75 days

butalbital, aspirin, caffeine, and codeine

48 units / 25 days

144 units / 75 days

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

**The limit criteria apply to both brand and generic, if available.*

REFERENCES

1. Allzital [package insert]. Canton, MS: Larken Laboratories, Inc.; March 2018.
2. Esgic [package insert]. Greenville, NC: Mayne Pharma; January 2018.
3. Fioricet [package insert]. Irvine, CA: Nexgen Pharma, Inc.; February 2018.
4. Fioricet with Codeine [package insert]. Parsippany, NJ: Watson Pharma, Inc.; September 2014.
5. Fiorinal [package insert]. Parsippany, NJ: September Pharma, Inc.; September 2014.
6. Fiorinal with Codeine [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; August 2017.
7. Vanatol Syrup [package insert]. Arlington, TX: GM Pharmaceuticals, Inc.; June 2017.
8. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed June 2018.
9. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed June 2018.
10. Beithon J, Gallenberg M, Johnson K, et al. Institute for Clinical Systems Improvement. Diagnosis and Treatment of Headache. https://www.icsi.org/guidelines__more/catalog_guidelines_and_more/catalog_guidelines/catalog_neurological_guidelines/headache/. Updated January 2013. Accessed June 2018.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

FORTAMET
(metformin extended-release)

GLUMETZA
(metformin extended-release)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Fortamet

Fortamet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Glumetza

Glumetza is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Important Limitations of Use

Glumetza should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has experienced an intolerance to generic Glucophage XR

REFERENCES

1. Fortamet [package insert]. Florham Park, NJ: Shionogi, Inc.; November 2017.
2. Glumetza [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; March 2018.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed July 2018.
4. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed July 2018.

Proposed Revision to Fortamet/Glumetza Generic Criteria Questions

Does the patient have a history of a trial of metformin ER (generic Glucophage XR)? Yes No

If yes, select the duration of trial: 30 day trial \geq 12 week trial

Will the medical record (e.g., chart notes, laboratory values) provide documentation of an inadequate response to metformin ER (generic Glucophage XR) as evidenced by a Hemoglobin A1c level above patient's goal for patient with diabetes diagnosis be submitted to with this form? Yes No

Will the medical record (e.g., chart notes, laboratory values) provide documentation of an intolerance to metformin ER (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction) be submitted with this form? Yes No

Will the medical record (e.g., chart notes, laboratory values) provide documentation of an allergic reaction to any inactive ingredients contained in generic Glucophage XR? Yes No

Does the patient have a history of a trial of metformin immediate-release (IR)? Yes No

If yes, select the duration of trial: 30 day trial \geq 12 week trial

Will the medical record (e.g., chart notes, laboratory values) provide documentation of an inadequate response to metformin IR as evidenced by a Hemoglobin A1c level above patient's goal for patient with diabetes diagnosis be submitted with this form? Yes No

Will the medical record (e.g., chart notes, laboratory values) provide documentation of an intolerance to metformin IR which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction) be submitted with this form? Yes No

****Please note: Chart documentation of the above is required to be submitted along with this fax**

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

ONFI
(clobazam)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Onfi (clobazam) is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in a patient 2 years of age or older

REFERENCES

1. Onfi [package insert]. Deerfield, IL: Lundbeck Inc.; December 2016.
2. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed May 2017.
3. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed May 2017.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

ORILISSA
(elagolix)

Status: CVS Caremark Criteria

Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Orilissa is indicated for the management of moderate to severe pain associated with endometriosis.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has the diagnosis of moderate to severe pain associated with endometriosis

AND

- The patient has not received the maximum recommended treatment course of 12 months of Lupron Depot or Lupaneta Pack or 6 months of Synarel or Zoladex

AND

- The patient will receive 150 mg once daily of the requested drug

AND

- The patient has not already received greater than or equal to 24 months of therapy of the requested drug

OR

- The patient will receive 200 mg twice daily of the requested drug

AND

- The patient has not already received greater than or equal to 6 months of therapy of the requested drug

REFERENCES

1. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; August 2018.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed August 2018.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed August 2018.
4. Schrager S, Falleroni J, Edgoose J. Evaluation and treatment of endometriosis. Am Fam Physician. 2013 Jan 15;87(2):107-13.
5. Management of endometriosis. Practice Bulletin No. 114. American College of Obstetricians and Gynecologists. Obstet Gynecol 2010;116:223-36.

ENHANCED SPECIALTY GUIDELINE MANAGEMENT

DMARD Combination for the Treatment of Rheumatoid Arthritis

**Actemra, Cimzia, Enbrel, Humira, Inflectra, Kevzara, Kineret, Olumiant, Oencia
Remicade, Renflexis, Simponi, Simponi Aria, Xeljanz, Xeljanz XR**

PROGRAM RATIONALE: The intent of the criteria is to provide coverage for branded biologic disease modifying antirheumatic drugs (DMARDs) for members who have maximized the use of non-biologic generic DMARDs for the treatment of rheumatoid arthritis. For this program, all branded specialty medications approved for the treatment of rheumatoid arthritis (Actemra, Cimzia, Enbrel, Humira, Inflectra, Kevzara, Kineret, Olumiant, Oencia, Remicade, Renflexis, Simponi, Simponi Aria, Xeljanz, Xeljanz XR) are targeted.

STEP THERAPY CRITERIA

If the member has inadequate response, intolerance or contraindication to treatment with generic DMARD medications, the requested branded medication will be approved, provided that the member has met all criteria for approval on all programs implemented for the client. **These step therapy criteria only apply to adult members who have not received treatment with any branded biologic or targeted synthetic DMARD for the treatment of rheumatoid arthritis.**

Coverage for a requested branded biologic disease modifying antirheumatic drugs (DMARDs) is provided when the member meets one of the following (criteria set A or B):

- A. Member has previously received a branded biologic or targeted synthetic DMARD for rheumatoid arthritis (RA)
- B. Member has not previously received a branded biologic or targeted synthetic DMARD for RA and meets one of the following (criteria set 1 or 2):
 - 1. Member has failed to achieve a low disease activity after a 3-month trial of a treatment regimen of methotrexate (MTX) at a maximum titrated dose of 20 mg per week and meets any of the following conditions:
 - a. Member has failed treatment with at least one other non-biologic DMARD (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose
 - b. Member has experienced an intolerable adverse event or has a contraindication to leflunomide, hydroxychloroquine, and/or sulfasalazine (see Appendix B)
 - c. Member has a moderate to high disease activity with poor prognostic feature(s) (see Appendix C)
 - 2. Member has experienced an intolerable adverse event or has a contraindication to MTX (see Appendix A) and meets any of the following conditions:
 - a. Member has failed treatment with another non-biologic DMARD (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s)
 - b. Member has experienced an intolerable adverse event or has a contraindication to leflunomide, hydroxychloroquine, and/or sulfasalazine (see Appendix B)
 - c. Member has a moderate to high disease activity with poor prognostic feature(s) (see Appendix C)

Reference number
1987-D

APPENDICES

Appendix A: Examples of contraindications to methotrexate

- Alcoholism, alcoholic liver disease or other chronic liver disease
- Blood dyscrasias (e.g. bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anemia)
- Breastfeeding
- Elevated liver transaminases
- History of intolerance or intolerable adverse event
- Hypersensitivity
- Interstitial pneumonitis or clinically significant pulmonary fibrosis
- Myelodysplasia
- Pregnancy
- Renal impairment
- Significant drug interaction

Appendix B: Examples of contraindications to leflunomide, hydroxychloroquine, and/or sulfasalazine

- Alcoholism, alcoholic liver disease or other chronic liver disease
- Blood dyscrasias (e.g. bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anemia)
- Breastfeeding
- Chronic liver disease
- Elevated liver transaminases
- Hypersensitivity
- Intestinal or urinary obstruction
- History of intolerance or intolerable adverse event
- Porphyria
- Pregnancy
- Presence of retinal or visual field changes attributable to any 4-aminoquinoline compound

Appendix C: Examples of poor prognostic features

- Functional limitation based on Health Assessment Questionnaire (HAQ) score or other valid functional status measures
- Extraarticular disease (e.g., presence of rheumatoid nodules, RA vasculitis, Felty's syndrome)
- Positive rheumatoid factor or anti-cyclic citrullinated peptide antibodies
- Bony erosions by radiograph

Note: Submission of chart notes detailing the outcomes of treatment, intolerable adverse event(s) experienced, contraindication(s), or exclusion(s) to treatment with prerequisite product(s) is required (where applicable).

REFERENCES

1. DRUGDEX® System [Internet database]. Ann Arbor, MI: Truven Health Analytics. Updated periodically. Accessed August 30, 2017.
2. Goekoop-Ruiterman YP, de Vries-Bouwstra JK, Allaart CF, et al. Clinical and radiographic outcomes of four different treatment strategies in patients with early rheumatoid arthritis (the BeSt study): a randomized, controlled trial. *Arthritis Rheum.* 2005;52:3381–90.
3. Graudal N, Jurgens G. Similar effects of disease-modifying antirheumatic drugs, glucocorticoids, and biologic agents on radiographic progression in rheumatoid arthritis: meta-analysis of 70 randomized placebo-controlled or drug-controlled studies, including 112 comparisons. *Arthritis Rheum.* 2010;62:2852–63.
4. Ma MH, Kingsley GH, Scott DL. A systematic comparison of combination DMARD therapy and tumour necrosis inhibitor therapy with methotrexate in patients with early rheumatoid arthritis. *Rheumatology (Oxford).* 2010;49:91–8.
5. Methotrexate tablets [package insert]. Sellersville, PA: Teva Pharmaceuticals USA; February 2010.

Reference number
1987-D

6. Moreland LW, O'Dell JR, Paulus HE, et al. A randomized comparative effectiveness study of oral triple therapy versus etanercept plus methotrexate in early aggressive rheumatoid arthritis: the Treatment of Early Aggressive Rheumatoid Arthritis trial. *Arthritis Rheum.* 2012;64:2824–35.
7. O'Dell JR, Mikuls TR, Taylor TH, et al. Therapies for active rheumatoid arthritis after methotrexate failure. *N Engl J Med.* 2013;369:307-18.
8. Saag KG, Teng GG, Patkar NM, Anuntiyo J, Finney C, Curtis JR. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum.* Jun 15 2008;59(6):762-84.
9. Sing JA, Furst DE, Bharat A, et al. 2012 Update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care Res.* 2012;64:625-39.
10. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update. *Rhem Dis.* 2014;73:492-509.
11. Van Vollenhoven RF, Geborek P, et al. Conventional combination treatment versus biological treatment in methotrexate-refractory early rheumatoid arthritis: 2 year follow-up of the randomised, nonblinded, parallel-group Swefot trial. *Lancet.* 2012;379:1712–20.

Reference number
2650-A

SPECIALTY GUIDELINE MANAGEMENT

GALAFOLD (migalastat)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Galafold is indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Fabry disease with an amenable galactosidase alpha gene (GLA) variant

Indefinite authorization may be granted for treatment of Fabry disease with an amenable galactosidase alpha gene (GLA) variant when all of the following criteria are met:

- A. The diagnosis of Fabry disease was confirmed by enzyme assay demonstrating a deficiency of alpha-galactosidase enzyme activity or by genetic testing, or the member is a symptomatic obligate carrier.
- B. Member has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Galafold [package insert]. Cranbury, NJ: Amicus Therapeutics U.S., Inc.; August 2018.
2. Desnick RJ, Brady RO. Fabry disease in childhood. *J Pediatr.* 2004;144(5 Suppl):S20-S26.
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Reference number(s)
2787-A

SPECIALTY GUIDELINE MANAGEMENT

LORBRENA (lorlatinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Lorbrena is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on:

- Crizotinib and at least one other ALK inhibitor for metastatic disease; or
- Alectinib as the first ALK inhibitor therapy for metastatic disease; or
- Ceritinib as the first ALK inhibitor therapy for metastatic disease

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for treatment of metastatic NSCLC when all of the following criteria are met:

- A. The disease is anaplastic lymphoma kinase (ALK)-positive
- B. The disease has progressed on any of the following therapies for metastatic disease:
 1. Crizotinib and at least one other ALK inhibitor
 2. Alectinib as the first ALK inhibitor therapy
 3. Ceritinib as the first ALK inhibitor therapy

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCE

1. Lorbrena [package insert]. New York, NY: Pfizer, Inc.; November 2018.

SPECIALTY GUIDELINE MANAGEMENT

VITRAKVI (larotrectinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Vitrakvi is indicated for the treatment of adult and pediatric patients with solid tumors that:

- have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation,
- are metastatic or where surgical resection is likely to result in severe morbidity, and
- have no satisfactory alternative treatments or that have progressed following treatment.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Solid tumors with a NTRK gene fusion

Authorization of 12 months may be granted for treatment of solid tumors when all of the following criteria are met:

- A. The tumors have a NTRK gene fusion without a known acquired resistance mutation, as demonstrated by laboratory testing (e.g., next-generation sequencing [NGS] or fluorescence in situ hybridization [FISH]).
- B. The disease is metastatic or surgical resection is likely to result in severe morbidity.
- C. No satisfactory alternative treatments are available or disease has progressed following standard systemic treatment for the disease.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Vitrakvi [package insert]. Stamford, CT: Loxo Oncology, Inc.; November 2018.

Reference number(s)
2640-H

SPECIALTY QUANTITY LIMIT PROGRAM

MULPLETA (lusutrombopag)

I. PROGRAM DESCRIPTION

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

II. COVERED QUANTITIES

Medication	Standard Limit	FDA-recommended dosing
Mulpleta (lusutrombopag) 3 mg tablets	7 per 14 days	3 mg orally once daily with or without food for 7 days

III. REFERENCE

- Mulpleta [package insert]. Florham Park, NJ: Shionogi Inc.; July 2018.

Reference number(s)
2042-A

SPECIALTY GUIDELINE MANAGEMENT

Intravenous Immune Globulin (IVIG):

Bivigam[®], Carimune[®] NF, Flebogamma[®] DIF, Gammagard[®] Liquid, Gammagard[®] S/D, Gammaked[™], Gammaplex[®], Gamunex[®]-C, Octagam[®], Panzyga[®], and Privigen[®]

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Primary immunodeficiency
2. Idiopathic thrombocytopenic purpura (ITP)
3. Chronic inflammatory demyelinating polyneuropathy
4. Multifocal motor neuropathy
5. Kawasaki syndrome
6. B-cell chronic lymphocytic leukemia (CLL)^{6,7}

B. Compendial Uses

1. Prophylaxis of bacterial infections in pediatric human immunodeficiency virus (HIV) infection¹⁵⁻¹⁹
2. Prophylaxis of bacterial infections in bone marrow transplant (BMT)/hematopoietic stem cell transplant (HSCT) recipients
3. Dermatomyositis
4. Polymyositis
5. Myasthenia gravis
6. Guillain-Barré syndrome
7. Lambert-Eaton myasthenic syndrome
8. Fetal/neonatal alloimmune thrombocytopenia
9. Parvovirus B19-induced pure red cell aplasia
10. Stiff-person syndrome
11. Management of immune checkpoint inhibitor-related nervous system adverse events

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

A. Primary immunodeficiency

1. Diagnostic test results (when applicable)
 - a. Copy of laboratory report with serum immunoglobulin levels: IgG, IgA, IgM, and IgG subclasses
 - b. Vaccine response to pneumococcal polysaccharide vaccine (post-vaccination *Streptococcus pneumoniae* antibody titers)
 - c. Pertinent genetic or molecular testing in members with a known genetic disorder
 - d. Copy of laboratory report with lymphocyte subset enumeration by flow cytometry

Reference number(s)
2042-A

2. IgG trough level for those continuing with IVIG therapy
- B. Secondary hypogammaglobulinemia (CLL, HIV, BMT/HSCT recipients)
 1. Copy of laboratory report with pre-treatment serum IgG level (when applicable)
- C. Chronic inflammatory demyelinating polyneuropathy (CIDP) and multifocal motor neuropathy (MMN)
 1. Pre-treatment electrodiagnostic studies (electromyography [EMG] or nerve conduction studies [NCS])
 2. For CIDP, pre-treatment cerebrospinal fluid (CSF) analysis (when available)
- D. Dermatomyositis and polymyositis
 1. Pre-treatment electrodiagnostic studies (EMG/NCS)
 2. Pre-treatment muscle biopsy report (when available)
- E. Lambert-Eaton Myasthenic Syndrome (LEMS)
 1. Neurophysiology studies (e.g., electromyography) (when applicable)
 2. A positive anti- P/Q type voltage-gated calcium channel antibody test (when applicable)

III. CRITERIA FOR INITIAL APPROVAL

A. Primary Immunodeficiency

Initial authorization of 12 months may be granted for members with any of the following diagnoses:

1. Severe combined immunodeficiency (SCID) or congenital agammaglobulinemia (eg, X-linked or autosomal recessive agammaglobulinemia):
 - a. Diagnosis confirmed by genetic or molecular testing, or
 - b. Pretreatment IgG level < 200 mg/dL, or
 - c. Absence or very low number of T cells (CD3 T cells < 300/microliter) or the presence of maternal T cells in the circulation (SCID only)
2. Wiskott-Aldrich syndrome, DiGeorge syndrome, or ataxia-telangiectasia (or other non-SCID combined immunodeficiency):
 - a. Diagnosis confirmed by genetic or molecular testing (if applicable), and
 - b. History of recurrent bacterial infections (eg, pneumonia, otitis media, sinusitis, sepsis, gastrointestinal), and
 - c. Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A)
3. Common variable immunodeficiency (CVID):
 - a. Age 4 years or older
 - b. Other causes of immune deficiency have been excluded (eg, drug induced, genetic disorders, infectious diseases such as HIV, malignancy)
 - c. Pretreatment IgG level < 500 mg/dL or ≥ 2 SD below the mean for age
 - d. History of recurrent bacterial infections
 - e. Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A)
4. Hypogammaglobulinemia (unspecified), IgG subclass deficiency, selective IgA deficiency, selective IgM deficiency, or specific antibody deficiency:
 - a. History of recurrent bacterial infections
 - b. Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A)
 - c. Any of the following pre-treatment laboratory findings:
 - i. Hypogammaglobulinemia: IgG < 500 mg/dL or ≥ 2 SD below the mean for age
 - ii. Selective IgA deficiency: IgA level < 7 mg/dL with normal IgG and IgM levels
 - iii. Selective IgM deficiency: IgM level < 30 mg/dL with normal IgG and IgA levels
 - iv. IgG subclass deficiency: IgG1, IgG2, or IgG3 ≥ 2 SD below mean for age assessed on at least 2 occasions; normal IgG (total) and IgM levels, normal/low IgA levels
 - v. Specific antibody deficiency: normal IgG, IgA and IgM levels
5. Other predominant antibody deficiency disorders must meet a., b., and c.i. in section 4. above.
6. Other combined immunodeficiency must meet criteria in section 2. above.

Reference number(s)
2042-A

Re-authorization of 24 months may be granted when the following criteria are met:

1. A reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy, AND
2. IgG trough levels are monitored at least yearly and maintained at or above the lower range of normal for age (when applicable for indication), OR
3. The prescriber will re-evaluate the dose of IVIG and consider a dose adjustment (when appropriate).

Gammagard Liquid, Gamunex-C, and Gammaked may be administered intravenously or subcutaneously for primary immunodeficiency.

B. Myasthenia Gravis

1. Authorization of 1 month may be granted to members who are prescribed IVIG for worsening weakness, acute exacerbation, or in preparation for surgery.
 - a. Worsening weakness includes an increase in any of the following symptoms: diplopia, ptosis, blurred vision, difficulty speaking (dysarthria), difficulty swallowing (dysphagia), difficulty chewing, impaired respiratory status, fatigue, and limb weakness. Acute exacerbations include more severe swallowing difficulties and/or respiratory failure
 - b. Pre-operative management (eg, prior to thymectomy)
2. Authorization of 12 months may be granted to members with refractory myasthenia gravis who have tried and failed 2 or more of standard therapies (eg, corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, rituximab).

C. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

1. Initial authorization of 3 months may be granted when the following criteria are met:
 - a. Moderate to severe functional disability
 - b. The diagnosis was confirmed by electrodiagnostic studies and the evaluation of cerebrospinal fluid (CSF)
2. Re-authorization of 24 months may be granted when the following criteria are met:
 - a. Significant improvement in disability and maintenance of improvement since initiation of IVIG therapy
 - b. IVIG is being used at the lowest effective dose and frequency

D. Dermatomyositis or Polymyositis

1. Initial authorization of 3 months may be granted when the following criteria are met:
 - a. Diagnosis established by clinical features (eg, proximal weakness, rash), elevated muscle enzyme levels, electrodiagnostic studies, and muscle biopsy (when available); supportive diagnostic tests include autoantibody testing and muscle imaging (eg, MRI), and
 - b. Standard first-line treatments (corticosteroids or immunosuppressants) have been tried but were unsuccessful or not tolerated, or
 - c. Member is unable to receive standard first-line therapy because of a contraindication or other clinical reason.
2. Re-authorization of 12 months may be granted when the following criterion is met:
 - a. Significant improvement in disability and maintenance of improvement since initiation of IVIG therapy

Reference number(s)
2042-A

E. Idiopathic Thrombocytopenic Purpura (Immune Thrombocytopenia)

1. Newly diagnosed ITP (diagnosed within the past 3 months) or initial therapy: authorization of 1 month may be granted when the following criteria are met:
 - a. Children (< 18 years of age)
 - i. Significant bleeding symptoms (mucosal bleeding or other moderate/severe bleeding) or
 - ii. High risk for bleeding* (see Appendix B), or
 - iii. Rapid increase in platelets is required* (eg, surgery or procedure)
 - b. Adults (≥ 18 years of age)
 - i. Platelet count < 30,000/mcL, or
 - ii. Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding or rapid increase in platelets is required*, and
 - iii. Corticosteroid therapy is contraindicated and IVIG will be used alone or IVIG will be used in combination with corticosteroid therapy
2. Chronic/persistent ITP (≥ 3 months from diagnosis) or ITP unresponsive to first-line therapy: authorization of 6 months may be granted when the following criteria are met:
 - a. Platelet count < 30,000/mcL, or
 - b. Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding* or rapid increase in platelets is required*, and
 - c. Relapse after previous response to IVIG or inadequate response/intolerance/contraindication to corticosteroid or anti-D therapy
3. Adults with refractory ITP after splenectomy: authorization of 6 months may be granted when either of the following criteria is met:
 - a. Platelet count < 30,000/mcL, or
 - b. Significant bleeding symptoms
4. ITP in pregnant women: authorization through delivery may be granted to pregnant women with ITP.

* The member's risk factor(s) for bleeding (see Appendix B) or reason requiring a rapid increase in platelets must be provided.

F. B-cell Chronic Lymphocytic Leukemia (CLL)

1. Initial authorization of 6 months may be granted when the following criteria are met:
 - a. IVIG is prescribed for prophylaxis of bacterial infections.
 - b. Member has a history of recurrent sinopulmonary infections requiring intravenous antibiotics or hospitalization.
 - c. Member has a pretreatment serum IgG level <500 mg/dL.
2. Re-authorization of 6 months may be granted when a reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy.

G. Prophylaxis of Bacterial Infections in HIV-Infected Pediatric Patients

1. Initial authorization of 6 months may be granted to pediatric members with HIV infection when the following criteria are met:
 - a. Member is ≤ 12 years of age.
 - b. IVIG is prescribed for primary prophylaxis of bacterial infections and pretreatment serum IgG < 400 mg/dL, or
 - c. IVIG is prescribed for secondary prophylaxis of bacterial infections for members with a history of recurrent bacterial infections (> 2 serious bacterial infections in a 1-year period)
2. Re-authorization of 6 months may be granted when a reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy.

H. Prophylaxis of Bacterial Infections in BMT/HSCT Recipients

Reference number(s)
2042-A

1. Initial authorization of 6 months may be granted to members who are BMT/HSCT recipients when the following criteria are met:
 - a. IVIG is prescribed for prophylaxis of bacterial infections.
 - b. Either of the following:
 - i. IVIG is requested within the first 100 days post-transplant.
 - ii. Member has a pretreatment serum IgG < 400 mg/dL.
2. Re-authorization of 6 months may be granted when a reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy.

I. Multifocal Motor Neuropathy (MMN)

1. Initial authorization of 3 months may be granted when the following criteria are met:
 - a. Weakness without objective sensory loss in 2 or more nerves
 - b. The diagnosis was confirmed by electrodiagnostic studies
2. Re-authorization of 24 months may be granted when significant improvement in disability and maintenance of improvement have occurred since initiation of IVIG therapy

J. Guillain-Barre Syndrome (GBS)

Authorization of 2 months total may be granted for the treatment of GBS.

K. Lambert-Eaton Myasthenic Syndrome (LEMS)

Authorization of 6 months may be granted for LEMS when the diagnosis has been confirmed by either of the following:

1. Neurophysiology studies (e.g., electromyography)
2. A positive anti- P/Q type voltage-gated calcium channel antibody test

L. Kawasaki Syndrome

Authorization of 1 month may be granted for pediatric members with Kawasaki syndrome.

M. Fetal/Neonatal Alloimmune Thrombocytopenia (F/NAIT)

Authorization of 6 months may be granted for treatment of F/NAIT.

N. Parvovirus B19-induced Pure Red Cell Aplasia (PRCA)

Authorization of 6 months may be granted for parvovirus B19-induced PRCA.

O. Stiff-person Syndrome

Authorization of 6 months may be granted for treatment of stiff-person syndrome.

P. Management of immune checkpoint inhibitor-related nervous system adverse events

Authorization of 1 month may be granted for management of immune checkpoint-inhibitor toxicities when all of the following criteria are met:

1. Member has experienced a moderate or severe adverse event to a PD-1 or PD-L1 inhibitor (eg, pembrolizumab, nivolumab, atezolizumab, avelumab, durvalumab)
2. The offending medication has been held or discontinued
3. Member experienced one or more of the following nervous system adverse events: pneumonitis, myasthenia gravis, peripheral neuropathy, encephalitis or transverse myelitis

IV. CONTINUATION OF THERAPY

Authorization may be granted for continuation of therapy when either the following criteria is met:

- A. For conditions with reauthorization criteria listed under section III: Members who are currently receiving IVIG therapy must meet the applicable reauthorization criteria for the member's condition.

Reference number(s)
2042-A

B. For all other conditions, all members (including new members) must meet initial authorization criteria.

V. OTHER

When Gammagard Liquid, Gamunex-C and Gammaked will be administered subcutaneously, they may be approved for primary immunodeficiency only.^{5,8,11}

VI. APPENDICES

Appendix A: Impaired Antibody Response to Pneumococcal Polysaccharide Vaccine

- Age 2 years and older: impaired antibody response demonstrated to vaccination with a pneumococcal polysaccharide vaccine
- Not established for children less than 2 years of age
- Excludes the therapy initiated in the hospital setting

Appendix B: Examples of Risk Factors for Bleeding (not all inclusive)

- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidity (eg, peptic ulcer disease, hypertension)
- Mandated anticoagulation therapy
- Profession or lifestyle predisposes patient to trauma (eg, construction worker, fireman, professional athlete)

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Pharmacy and Therapeutics (P&T) Committee Meeting

Wednesday, February 13th 2019, 6:30 p.m. to 8:00 p.m.

Agenda

<u>Topic:</u>	<u>Presenter:</u>
<p>1. Welcome</p> <ul style="list-style-type: none"> • Call to Order • Roll Call 	<p>Carl Antolick III, Chair</p>
<p>2. Conflict of Interest Statement</p>	<p>Carl Antolick III, Chair</p>
<p>3. Old Business</p> <ul style="list-style-type: none"> • Formulary Development and Management at CVS Caremark • Minutes from August 21, 2018 Meeting* • Recent Plan Formulary Decisions 	<p>Carl Antolick III, Chair</p>
<p>4. Formulary Updates*</p> <ul style="list-style-type: none"> • Formulary Drug Exclusions • Tier Changes <ul style="list-style-type: none"> ○ Downtier ○ Uptier • Formulary Additions 	<p>Carl Antolick III, Chair</p> <p>Heather Renee Jarnigan, CVS</p> <p>Heather Renee Jarnigan, CVS</p> <p>Heather Renee Jarnigan, CVS</p>
<p>5. Utilization Management Policy Review*</p> <ul style="list-style-type: none"> • New Policies Under Consideration <ul style="list-style-type: none"> ○ Butalbital Containing Analgesics (Brand/Generics) Policy ○ Fortamet, Glumetza Policy (Proposed Revisions) ○ Onfi Policy ○ Orilissa Policy ○ Rheumatoid Arthritis Enhanced SGM 	<p>Carl Antolick III, Chair</p> <p>Stephanie Morrison, CVS</p>
<p>6. Adjourn</p> <ul style="list-style-type: none"> • Next Meeting: <i>Wednesday, May 15th 2019 from 6:30 to 8:00 PM via webinar</i> 	<p>Carl Antolick III, Chair</p>