MAY 15, 2019

North Carolina State Health Plan
FOR TEACHERS AND STATE EMPLOYEES
A Division of the Department of State Treasurer

STATE TREASURER OF NORTH CAROLINA
DALE R. FOLWELL, CPA

PHARMACY AND THERAPEUTICS (P&T) COMMITTEE MEETING

NORTH CAROLINA STATE HEALTH PLAN

3200 ATLANTIC AVENUE, RALEIGH, NC 27604

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Pharmacy and Therapeutics (P&T) Committee Meeting

Wednesday, May 15th, 2019 from 6:30 p.m. to 8:00 p.m.

Agenda

	Topic:	*Presenter:*
1.	**Welcome**	Carl Antolick III, Chair
	• Call to Order	
	• Roll Call	
2.	**Conflict of Interest Statement**	Carl Antolick III, Chair
3.	**Old Business**	Carl Antolick III, Chair
	• Formulary Development and Management at CVS Caremark	
	• Minutes from February 13th, 2019 Meeting*	
	• Recent Plan Formulary Decisions	
4.	**Formulary Updates***	Carl Antolick III, Chair
	• Formulary Drug Exclusions	Heather Renee Jarnigan, CVS
	• Tier Changes	Heather Renee Jarnigan, CVS
	○ Downtier	
	○ Uptier	
	• Formulary Additions	Heather Renee Jarnigan, CVS
5.	**Utilization Management Policy Review***	Carl Antolick III, Chair
	• New Policies Under Consideration	Stephanie Morrison, CVS
	○ Xiidra Policy	
	○ Specialty Quantity Limit Diacomit	
	○ Elzonris Specialty Guideline Management	
	○ Specialty Quantity Limit HIV Medications	
6.	**Adjourn**	Carl Antolick III, Chair
	• Next Meeting: *August 14th, 2019 from 6:30 to 8:00 PM via webinar*	

*Requires a recommendation from the P&T Committee

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 participation[1] 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 products[1] 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.

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

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

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

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PHARMACY AND THERAPEUTICS (P&T) COMMITTEE
February 13, 2019

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 Wednesday, February 13, 2019, 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
Matthew K. Flynn, MD, Founder, Family Dermatology
Jennifer Burch, PharmD, Owner, Central Compounding Center
John J. Engemann, MD, Infectious Disease Specialist, Raleigh Infectious Disease Associates, PA
Joseph Shanahan, MD, Owner, Shanahan Rheumatology & Immunotherapy

MEMBERS ABSENT:
David Konanc, MD, Neurologist, Raleigh Neurology Associates
John Anderson, MD, MPH, Chief Medical Officer, Duke Primary Care

PLAN & VENDOR STAFF:
Carl Antolick III, PharmD, Clinical Pharmacist (Chair), State Health Plan
Tracy Linton, MPH, Sr. Director, Plan Benefits, 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: ACANYA, BENZACLIN, ONEXTON, VELTIN, ZIANA, JENTADUETO, JENTADUETO XR, TRADJENTA, CAMBIA, CONTRAVE, SORILUX, ACTICLATE, TARGADOX, ZUPLENZ, VANATOL LQ, TIROSINT, AVENOVA, ZEMAIRA, ELOCTATE, LUPRON DEPOT, FASENRA, ALPROLIX, & CIMZIA; moving the following branded products to non-preferred status: LUPRON DEPOT KIT 3.75MG AND 11.25MG, ZOLADEX, FENTORA, WELCHOL PAK 3.75GM,

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& PYRIDIUM tablet 100MG; and adopting the following new utilization management criteria: Corticosteroid-Pulmicort 1mg Post Limit Policy & Select Medical Devices Initial Prior Authorization. All these changes were approved by the Committee during May's meeting and subsequently went into effect January 1, 2019.

Minutes from Previous P&T Meeting:
The Chairperson asked the P&T Committee members to review the October 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 introduced CVS Caremark's Clinical Advisors Heather Renee Jarnigan, RPh, & Stephanie Morrison, PharmD, BCPS whom would be presenting CVS Caremark's Quarterly Formulary Updates which will be effective April 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: ZYTIGA, EPOGEN, PROCRIT, & Solubiomix's BUTALBITAL/ACETAMINOPHEN 50-300 MG capsules, & DICLOFENAC GEL 1%. 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. 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 up tiered. They include: ATRALIN GEL 0.05%, COREG CR, ESTRACE VAGINAL CREAM 0.01%, LUZUCREAM 1%, UCERIS, MESTINON TIMESPAN, & TOPICORT. 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 down tiered. They include: COPAXONE SYRINGES 20MG/ML, MULPLETA TABLETS 3MG, DUPIXENT 200MG/1.14ML, & ARISTADA INITIO. There was no opposition from the Committee members so the changes were approved as presented.

Ms. Jarnigan identified all the medications that were being removed from CVS's New-to-Market block and would be available as covered products effective April 1, 2019, 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: XERAVA, ARIKAYCE, LUMOXITI, LIBTAYO, ONPATTRO, EPIDIOLEX, OXERVATE, JULUCA, LORBRENA, GALAFOLD, MULPLETA, VITRAKVI, NUZYRA, REVCOVI, AEMCOLO, GAMIFANT, FIRDAPSE, ANDEXXA, LOKELMA, ORILISSA, INTRAROSA, DVORAH, VANCOMYCIN, KISQALI, SIKLOS, DILTIAZEM, EMGALITY,TRESIBA, DIVIGEL, PROMACTA, XARELTO, HIZENTRA, CYTOGAM, ZORTRESS, ANAVIP, TYLACTIN, AMINO ACID, SODIUM BICARBONATE, XOLAIR, DUPIXENT, & RETACRIT. There was no opposition from the Committee members so the additions were approved as presented.

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The Committee then reviewed new utilization management policies that were under consideration for adoption. They included: Butalbital Containing Analgesics (Brand/Generics) Policy, Fortamet, Glumetza Policy (Proposed Revisions), Onfi Policy, Orilissa Policy, & Rheumatoid Arthritis Enhanced SGM. Dr. Shanahan objected to the Rheumatoid Arthritis Enhanced SGM policy stating that there was new data to support treatment with biologics over other oral therapies. Per his guidance the Plan did not enact the Rheumatoid Arthritis Enhanced SGM policy. There was no other opposition from the Committee members regarding the other policies, so they would be enacted on April 1, 2019.

Adjourn

Dr. Antolick addressed the Committee by thanking them for their service and informed them that the next meeting would be held on May 15th at 6:30 P.M. via webinar. The meeting was adjourned at approximately 8:00 P.M. (EST).

Carl Antolick III, Chair

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RECENT PLAN FORMULARY DECISIONS

(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, 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, DVORAH, VANCOMYCIN, KISQALI, SIKLOS, DILTIAZEM, EMGALITY, TRESIBA, DIVIGEL, PROMACTA, XARELTO, HIZENTRA, CYTOGAM, ZORTRESS, ANAVIP, TYLACTIN, AMINO ACID, SODIUM BICARBONATE, XOLAIR, DUPIXENT, & RETACRIT.
5. **UTILIZATION MANAGEMENT**
    a. Addition of new prior authorizations, step therapy, or quantity limits to ensure clinically appropriate usage of certain medications.
    b. Policies enacted:
        i. Butalbital Containing Analgesics (Brand/Generics) Policy, Fortamet/Glumetza Policy (Proposed Revisions), Onfi Policy, & Orilissa Policy.

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Exclusions & Tier Changes

Therapeutic Category/ Subcategory	Drug	Specialty	Rationale/Alternatives	Change Type	Tier Change	# Utilizers (6 mo)
Anti-Infectives/ Hepatitis B Agents	**EPIVIR HBV** (lamivudine)	Y	Availability of other options for the treatment of chronic hepatitis B virus (HBV) infection. Preferred options include entecavir tablet, lamivudine, Baraclude solution (entecavir) and Viread (tenofovir disoproxil fumarate).	Exclusion - ACSF	Tier 3--> Not Covered/ ACSF	0
Anti-Infectives/ Hepatitis B Agents	**VEMLIDY** (tenofovir alafenamide fumarate)	Y	Availability of other options for the treatment of chronic hepatitis B virus (HBV) infection. Preferred options include entecavir tablet, lamivudine, Baraclude solution (entecavir) and Viread (tenofovir disoproxil fumarate).	Exclusion - ACSF	Tier 2/ ACSF--> Not Covered/ ACSF	25
Hematologic/ Hematopoietic Growth Factors	**ZARXIO** (fligrastim)	Y	Availability of another short-acting colony-stimulating factor option for those who are receiving myelosuppressive anti-cancer therapy. The preferred option is Nivestym (filgrastim-aafi).	Exclusion - ACSF	Tier 2/ ACSF--> Not Covered/ ACSF	25
Immunologic Agents/ Immunosuppressants/ Rapamycin Derivatives	**ZORTRESS** (everolimus)	Y	Availability of a generic option for the prophylaxis of organ rejection in kidney and liver transplant recipients. The preferred option is sirolimus.	Exclusion - ACSF	Tier 3--> Not Covered/ ACSF	3
Anti-Infectives/ Hepatitis B Agents	**BARACLUDE TABLETS** (entecavir)	Y	Availability of other options for the treatment of chronic hepatitis B virus (HBV) infection. Preferred options include entecavir tablet, lamivudine, Baraclude solution (entecavir), and Viread (tenofovir disoproxil fumarate).	Exclusion - ACSF	Tier 3--> Not Covered/ ACSF	4

Exclusions & Tier Changes

Therapeutic Category/ Subcategory	Drug	Specialty	Rationale/Alternatives	Change Type	Tier Change	# Utilizers (6 mo)
Anti-Infectives/ Hepatitis B Agents	**HEPSERA** (adefovir dipivoxil)	Y	Availability of other options for the treatment of chronic hepatitis B virus (HBV) infection. Preferred options include entecavir tablet, lamivudine, Baraclude solution (entecavir), and Viread (tenofovir disoproxil fumarate).	Exclusion - ACSF	Tier 3--> Not Covered/ ACSF	1
Endocrine and Metabolic/ Fertility Regulators/ Ovulation Stimulants, Gonadotropins	**CHORIONIC GONADOTROPIN** (chorionic gonadotropin, human)	Y	Availability of other options for the treatment of induction of ovulation and pregnancy in women. The preferred option is Ovidrel (choriogonadotropin alfa).	Exclusion - ACSF	Tier 3--> Not Covered/ ACSF	7
Endocrine and Metabolic/ Fertility Regulators/ Ovulation Stimulants, Gonadotropins	**NOVAREL** (chorionic gonadotropin, human)	Y	Availability of other options for the treatment of induction of ovulation and pregnancy in women. The preferred option is Ovidrel (choriogonadotropin alfa).	Exclusion - ACSF	Tier 3--> Not Covered/ ACSF	2
Endocrine and Metabolic/ Fertility Regulators/ Ovulation Stimulants, Gonadotropins	**PREGNYL** (chorionic gonadotropin, human)	Y	Availability of other options for the treatment of induction of ovulation and pregnancy in women. The preferred option is Ovidrel (choriogonadotropin alfa).	Exclusion - ACSF	Tier 3--> Not Covered/ ACSF	2
Hematologic/ Hematopoietic Growth Factors	**FULPHILA** (pegfilgrastim)	Y	Availability of other long-acting colony-stimulating factor options for those who are receiving myelosuppressive anti-cancer therapy. Preferred options include Neulasta (pegfilgrastim) and Udenyca (pegfilgrastim-cbqv).	Exclusion - ACSF	NTM Blocked--> Not Covered/ ACSF	0

Exclusions & Tier Changes

Therapeutic Category/ Subcategory	Drug	Specialty	Rationale/Alternatives	Change Type	Tier Change	# Utilizers (6 mo)
Hematologic/ Hematopoietic Growth Factors	**GRANIX** (filgrastim)	Y	Availability of another short-acting colony-stimulating factor option for those who are receiving myelosuppressive anti-cancer therapy. The preferred option is Nivestym (filgrastim-aafi).	Exclusion - ACSF	Tier 3--> Not Covered/ ACSF	1
Immunologic Agents/ Immunosuppressants/ Antimetabolites	**CELLCEPT** (mycophenolate)	Y	Availability of generic options for the prophylaxis of organ rejection in transplant recipients. Preferred options include mycophenolate mofetil and mycophenolate sodium.	Exclusion - ACSF	Tier 3--> Not Covered/ ACSF	19
Immunologic Agents/ Immunosuppressants/ Antimetabolites	**MYFORTIC** (mycophenolate)	Y	Availability of generic options for the prophylaxis of organ rejection in renal transplant recipients. Preferred options include mycophenolate mofetil and mycophenolate sodium.	Exclusion - ACSF	Tier 3--> Not Covered/ ACSF	89
Immunologic Agents/ Immunosuppressants/ Rapamycin Derivatives	**RAPAMUNE TABS & SOL** (sirolimus)	Y	Availability of a generic option for the prophylaxis of organ rejection in renal transplant recipients and the treatment of lymphangioleiomyomatosis (LAM). The preferred option is sirolimus.	Exclusion - ACSF	Tier 2--> Not Covered/ ACSF	11
Immunologic Agents/ Immunosuppressants/ Calcineurin Inhibitors	**ASTAGRAF XL** (tacrolimus)	Y	Availability of generic options for the prophylaxis of organ rejection in transplant recipients. Preferred options on the Advanced Control Specialty Formulary include cyclosporine; cyclosporine, modified; and tacrolimus.	Exclusion - ACSF	Tier 3--> Not Covered/ ACSF	2

Exclusions & Tier Changes

Therapeutic Category/ Subcategory	Drug	Specialty	Rationale/Alternatives	Change Type	Tier Change	# Utilizers (6 mo)
Immunologic Agents/ Immunosuppressants/ Calcineurin Inhibitors	**ENVARSUS XR** (tacrolimus)	Y	Availability of generic options for the prophylaxis of organ rejection in transplant recipients. Preferred options include cyclosporine; cyclosporine, modified; and tacrolimus.	Exclusion - ACSF	NTM Blocked--> Not Covered/ ACSF	13
Analgesics/ NSAIDs	**ZORVOLEX** (diclofenac)	N	Availability of generic nonsteroidal anti-inflammatory agents (NSAIDs) for treating mild to moderate pain, or pain associated with osteoarthritis (OA). Preferred options include diclofenac sodium, meloxicam, and naproxen.	Hyperinflation exclusion	3--> Not Covered	78
Nutritional/ Supplements/ Medical Foods	**RHEUMATE** (folate, methylcobalamin [B12], curcuminoid turmerone complex	N	Availability of a generic option for folate supplementation during methotrexate therapy. The preferred option is folic acid.	Hyperinflation exclusion	3--> Not Covered	0
Nutritional/ Supplements/ Medical Foods	**FOSTEUM** (genistein, zinc chelazome, cholecalciferol)	N	Availability of generic options for treating osteopenia and osteoporosis. Preferred options include alendronate, ibandronate, and risedronate.	Hyperinflation exclusion	3--> Not Covered	0
Nutritional/ Supplements/ Medical Foods	**FOSTEUM PLUS** (calcium compounds phosphate, genistein aglycone, citrated zinc bisglycinate, trans-menaquinone-7, cholecalciferol)	N	Availability of generic options for treating osteopenia and osteoporosis. Preferred options include alendronate, ibandronate, and risedronate.	Hyperinflation exclusion	3--> Not Covered	0

Exclusions & Tier Changes

Therapeutic Category/ Subcategory	Drug	Specialty	Rationale/Alternatives	Change Type	Tier Change	# Utilizers (6 mo)
Nutritional/ Supplements/ Medical Foods	**VASCULERA** (diosmin glycoside, alka4-complex)	N	Availability of other options for dietary supplementation in maintaining the integrity of vein walls and decreasing inflammation to prevent progression to chronic venous disease (CVD). Consult doctor for preferred options.	Hyperinflation exclusion	3--> Not Covered	0
Topical/ Ophthalmic/ Anti-inflammatories/ Steroidal	**FML LIQUIFILM** (fluorometholone)	N	Availability of other options for treating inflammation within the eye. Preferred options include dexamethasone, prednisolone acetate 1%, Durezol (difluprednate), Flarex (fluorometholone), FML Forte (fluorometholone), FML S.O.P. (fluorometholone), Maxidex (dexamethasone), and Pred Mild (prednisolone acetate).	Hyperinflation exclusion	3--> Not Covered	3
Laxative, Osmotic/ Ammonium Detoxicant	**LACTULOSE PAK 10 GM** (only NDC 46600020003010)	N	Availability of other less expensive NDC's. Preferred options include Lactulose, Enulose, & Generlac solution 10 GM/15 ML	Hyperinflation exclusion	1--> Not Covered	3
Analgesics/ NSAIDs	**NAPROXEN SUSPENSION 125MG/5ML** (only NDC 66100060001805)	N	Availability of other less expensive NDC's. Preferred options include Naproxen solution 125MG/5 ML by Palmetto Pharmaceuticals, Inc.	Hyperinflation exclusion	2--> Not Covered	36
Central Nervous System/ Fibromyalgia	**SAVELLA** (milnacipran hydrochloride)	N	Availability of another option for the treatment of fibromyalgia. The preferred option is Lyrica (pregabalin).	Negative Tiering Change	2--> 3	127*

Exclusions & Tier Changes

Therapeutic Category/ Subcategory	Drug	Specialty	Rationale/Alternatives	Change Type	Tier Change	# Utilizers (6 mo)
Genitourinary/ Benign Prostatic Hyperplasia	**RAPAFLO** (silodosin)	N	Availability of generic options for the treatment of benign prostatic hyperplasia (BPH). Preferred options include alfuzosin ext-rel, doxazosin, silodosin, tamsulosin, and terazosin.	Negative Tiering Change	2--> 3	124
Gastrointestinal/ Inflammatory Bowel Disease/ Rectal Agents	**CANASA** (mesalamine)	N	Availability of other options for the treatment of ulcerative proctitis. Preferred options include hydrocortisone enema, mesalamine rectal suspension, and Cortifoam (hydrocortisone acetate foam).	Negative Tiering Change	2--> 3	105
Gastrointestinal/ Miscellaneous	**CARAFATE** (sucralfate)	N	Availability of a generic option for the treatment of active duodenal ulcers. The preferred option is sucralfate.	Negative Tiering Change	2--> 3	650
Cardiovascular/ Beta-Blocker/Diuretic Combinations	**TENORETIC** (atenolol/chlorthalidone)	N	Availability of other beta-blocker/diuretic combination medications for treating hypertension. Preferred options include atenolol/chlorthalidone, bisoprolol/hydrochlorothiazide, metoprolol/hydrochlorothiazide, Lopressor HCT (metoprolol/hydrochlorothiazide), and Ziac (bisoprolol/hydrochlorothiazide).	Negative Tiering Change	2--> 3	1
Genitourinary/ Erectile Dysfunction/ Phosphodiesterase Inhibitors	**CIALIS 2.5mg and 5 mg** (tadalafil)	N	Availability of generic options for the treatment of benign prostatic hyperplasia (BPH). Cialis (and generics) for use for erectile dysfunction remains a Plan Exclusion. Preferred options are sildenafil and tadalafil.	Negative Tiering Change	2--> 3	179

Exclusions & Tier Changes

Therapeutic Category/ Subcategory	Drug	Specialty	Rationale/Alternatives	Change Type	Tier Change	# Utilizers (6 mo)
Hematologic/ Hematopoietic Growth Factors	**NEULASTA** (pegfilgrastim)	Y	To provide a long-acting colony-stimulating factor option for those who are receiving myelosuppressive anti-cancer therapy.	Positive Tiering Change	Tier 6/ ACSF--> Tier 5/ ACSF	n/a
Topical/ Ophthalmic/ Retinal Disorders	**EYLEA VIA 2/0.05ML** (aflibercept)	Y	To provide an option for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy in patients with diabetic macular edema.	Positive Tiering Change	Tier 6/ ACSF--> Tier 5/ ACSF	n/a
Topical/ Ophthalmic/ Retinal Disorders	**LUCENTIS SOL 0.3MG** (ranibizumab)	Y	To provide an option for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization.	Positive Tiering Change	Tier 6/ ACSF--> Tier 5/ ACSF	n/a
Endocrine and Metabolic/ Antidiabetics/ Supplies	**V-GO** (disposable insulin delivery device)	N	To provide an option for continuous/basal and on-demand/bolus insulin delivery in insulin-dependent diabetes.	Positive Tiering Change	3--> 2	n/a

Formulary Additions

Therapeutic Category/ Subcategory	Drug	Specialty Flag	CVS Block Removal Date	Proposed NCSHP Tier	Comments	New Molecular Entity
Antineoplastic Agents/ Anti-CD123	**ELZONRIS** (tagraxofusp)	Y	2/13/19	6	Indicated for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older	Y
Anti-Infectives/ Antiretroviral Combinations	**CIMDUO** (lamivudine/tenofovir disoproxil fumarate)	Y	4/18/19	2	Indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg.	Y
Anti-Infectives/ Antiretroviral Agents/ Antiretroviral Combinations	**SYMFI** (efavirenz 600 mg /lamivudine/tenofovir disoproxil fumarate)	Y	4/18/19	2	Indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 40 kg.	Y
Anti-Infectives/ Antiretroviral Agents/ Antiretroviral Combinations	**SYMFI LO** (efavirenz 400 mg /lamivudine/tenofovir disoproxil fumarate)	Y	4/18/19	2	Indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg.	Y
Central Nervous System/ Anticonvulsants	**DIACOMIT** (stiripentol)	Y	5/1/19	6	Indicated for treatment of seizures associated with Dravet syndrome (DS) in patients 2 years of age and older.	Y
Hematologic/ Hematopoietic Growth Factors	**UDENYCA** (pegfilgrastim)	Y	5/1/19	4	To provide a long-acting colony-stimulating factor option for those who are receiving myelosuppressive anti-cancer therapy.	N

Formulary Additions

Therapeutic Category/ Subcategory	Drug	Specialty Flag	CVS Block Removal Date	Proposed NCSHP Tier	Comments	New Molecular Entity
Hematologic/ Hematopoietic Growth Factors	**NIVESTYM** (filgrastim)	Y	5/1/19	4	To provide a short-acting colony-stimulating factor option for those who are receiving myelosuppressive anti-cancer therapy.	N
Respiratory Agents/Pulmonary Fibrosis Agents	**ESBRIET 267 & 801 MG** (pirfenidone)	Y	5/4/2018	5	New tablet formulation available in 2018	N
Cardiovascular Agents/Pulmonary Hypertension	**ALYQ 20 MG** (tadalafil)	Y	2/6/19	4	Generic (tadalafil) for Adcirca	N
Cardiovascular Agents/Pulmonary Hypertension	**TADALAFIL TAB 20MG**	Y	3/1/19	4	Generic (tadalafil) for Adcirca	N
Anti-Infectives/ Glycopeptide	**VANCOMYCIN INJ 1.5/300**	N		3	New SSB	N
Antineoplastic Agents/ Monoclonal Antibodies	**TECENTRIQ INJ 840/14** (atezolizumab)	Y	3/20/19	6	New strength of product already on formulary	N

Formulary Additions

Therapeutic Category/ Subcategory	Drug	Specialty Flag	CVS Block Removal Date	Proposed NCSHP Tier	Comments	New Molecular Entity
Immunologic Agents/ Immunosuppressants/ Calcineurin Inhibitors	**PROGRAF GRA 0.2 & 1 MG** (tacrolimus)	Y	3/20/19	2	New SSB granule packets for suspension formulation; CVS Excludes from ACSF; Historically, NCSHP placed Prograf at tier 2.	N
Endocrine and Metabolic/ Estrogens/ Vaginal	**FEMRING 0.05/24H & 0.1MG/24** (estradiol acetate)	N	3/20/19	3	New strength of product already on formulary	N
Endocrine and Metabolic/ Antidiabetics/ Insulins	**NOVOLIN INJ FLEXPEN** (insulin regular [human])	N	3/20/19	2	Removal of Flexpen formulation from NTM block.	N
Antineoplastic Agents/ Cytoprotective Agents	**LEUCOVORIN INJ 500/50ML**	N	4/10/19	1	New generic available in the 500mg/50ml strength	N
Central Nervous System/ Antidepressants/ NMDA Receptor Antagonists	**SPRAVATO 56 & 84 MG** (esketamine)	Y	4/18/19	6	Esketamine, the S-enantiomer of ketamine, in a nasal sprayform indicated, in conjunction with an oral antidepressant, for the tx of treatment-resistent depression in adults. Has a REMS Program.	N
Topical/ Dermatology/ Antibiotics, Quinolone	**XEPI CREAM 1%** (ozenoxacin)	N	4/18/19	3	Indicated for the topical treatment of impetigo due to Staphylococcus aureus or Streptococcus pyogenes in adult and pediatric patients 2 months of age and older.	N

Utilization Management Policies

Policy Name	*Policy Type*
Specialty Quantity Limit HIV Medications	Quantity Limits
Elzonris SGM	Specialty Guideline Management
Xiidra Policy	Initial Prior Authorization
Specialty Quantity Limit Diacomit	Quantity Limits

Reference number(s)
1804-H

SPECIALTY QUANTITY LIMIT PROGRAM

HUMAN IMMUNODEFICIENCY VIRUS (HIV) MEDICATIONS

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 all FDA-approved indications 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
Aptivus (tipranavir) capsules 250 mg	120 per 30 days	• Adults: 500 mg with ritonavir twice daily • Pediatric patients: Based on body weight or body surface area not to exceed adult dose
Aptivus (tipranavir) oral solution 100 mg/mL	285 mL per 28 days	
Atripla (efavirenz 600 mg, emtricitabine 200 mg, and tenofovir disoproxil fumarate 300 mg) tablets	30 per 30 days	• One tablet once daily
Biktarvy (bictegravir 50mg, emtricitabine 200mg, and tenofovir alafenamide 25mg) tablets	30 per 30 days	• One tablet once daily
Cimduo (lamivudine 300mg and tenofovir disoproxil fumarate 300mg) tablets	30 per 30 days	• One tablet once daily
Combivir (lamivudine 150 mg and zidovudine 300 mg) tablets	60 per 30 days	• Adults and adolescents weighing ≥ 30 kg: one tablet twice daily • Pediatric patients: Based on body weight not to exceed adult doses
Complera (emtricitabine 200 mg, 25 mg rilpivirine, and 300 mg tenofovir disoproxil fumarate) tablets	30 per 30 days	• One tablet once daily
Crixivan (indinavir sulfate) capsules 200 mg	450 per 30 days	• 800 mg three times daily • 600 mg three times daily when administering - delavirdine 400 mg three times a day - itraconazole 200 mg twice daily concurrently or - ketoconazole concurrently - mild-to-moderate hepatic insufficiency due to cirrhosis • 1000 mg three times daily when co-administered with rifabutin
Crixivan (indinavir sulfate) capsules 400 mg	180 per 30 days	

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Medication	Standard Limit*	FDA-recommended dosing
Delstrigo (doravirine 100 mg, lamivudine 300 mg, and tenofovir disoproxil fumarate 300mg) tablets	30 per 30 days	• One tablet once daily • Co-administration with rifabutin: one tablet of Delstrigo once daily followed by one tablet of Pifeltro approximately 12 hours after the dose of Delstrigo
Descovy (emtricitabine 200 mg and tenofovir alafenamide 25 mg) tablets	30 per 30 days	• One tablet once daily
Dovato (dolutegravir 50mg and lamivudine 300mg) tablets	30 per 30 days	• One tablet once daily
Edurant (rilpivirine) tablets 25 mg	60 per 30 days	• One tablet once daily • Two tablets once daily when co-administered with rifabutin
Emtriva (emtricitabine) capsules 200 mg	30 per 30 days	• Adult patients: one capsule once daily • Pediatric patients: one capsule once daily
Emtriva (emtricitabine) oral solution 10 mg/mL	680 mL per 28 days	• Adult patients: 240 mg (24 mL) once daily • Pediatric patients aged 3 months to 17 years: 6 mg/kg up to a maximum of 240 mg (24 mL) once daily • Pediatric patients aged 0 to 3 months: 3 mg/kg once daily
Epivir (lamivudine) oral solution 10 mg/mL	900 mL per 30 days	• Adults and adolescents > 16 years of age: 150 mg twice daily or 300 mg once daily • Pediatric patients aged 3 months to 16 years: 4 mg/kg twice daily (up to a maximum of 150 mg twice a day)
Epivir (lamivudine) tablets 150 mg	60 per 30 days	
Epivir (lamivudine) tablets 300 mg	30 per 30 days	
Epzicom (abacavir 600 mg and lamivudine 300 mg) tablets	30 per 30 days	• One tablet once daily
Evotaz (atazanavir 300 mg and cobicistat 150 mg) tablets	30 per 30 days	• One tablet once daily
Fuzeon (enfuvirtide) inj 90 mg vial	60 per 30 days	• Adults: 90 mg twice daily • Pediatric patients (6 to 16 years of age): 2 mg/kg twice daily, not to exceed the adult dose
Genvoya (elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg, and tenofovir alafenamide 10 mg) tablets	30 per 30 days	• One tablet once daily
Intelence (etravirine) tablets 25 mg	120 per 30 days	• Adult patients: 200 mg twice daily • Pediatric patients (≥ 2 years and weighing at least 10 kg): 100 mg, 125 mg, 150 mg, or 200 mg, based on body weight
Intelence (etravirine) tablets 100 mg	120 per 30 days	
Intelence (etravirine) tablets 200 mg	60 per 30 days	
Invirase (saquinavir mesylate) capsules 200 mg	300 per 30 days	• 1000 mg twice daily

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Medication	Standard Limit*	FDA-recommended dosing
Invirase (saquinavir mesylate) tablets 500 mg	120 per 30 days	
Isentress (raltegravir) chewable tablets 25 mg	180 per 30 days	• Adult patients: 400 mg twice daily; 800 mg twice daily when coadministered with rifampin • Children and adolescents: 25-400 mg twice daily, based on body weight • Neonates: up to 15mg twice daily, based on body weight
Isentress (raltegravir) powder 100 mg packet	60 per 30 days	
Isentress (raltegravir) chewable tablets 100 mg	180 per 30 days	
Isentress (raltegravir) tablets 400 mg	120 per 30 days	
Isentress (raltegravir) HD tablets 600 mg	60 per 30 days	• 1200 mg (two 600 mg tablets) film-coated tablet orally, once daily
Juluca (dolutegravir-rilpivirine) tablets 50-25 mg	30 per 30 days	• One tablet once daily
Kaletra (lopinavir 80 mg/ritonavir 20 mg per mL) sol	390 per 30 days	• Adults: 800 mg/200 mg (in tablets or oral solution) given once daily or 400 mg/100 mg twice daily; 500 mg/125 mg (2 tablets of 200 mg/50 mg + 1 tablet of 100 mg/25 mg) twice daily or 520 mg/130 mg (6.5 mL of oral solution) twice daily when co-administered with efavirenz, nevirapine, or nelfinavir • Pediatric patients: Based on body weight and body surface area, up to a maximum dose of 400 mg/100 mg twice daily
Kaletra (lopinavir-ritonavir) tablets 100-25 mg	240 per 30 days	
Kaletra (lopinavir-ritonavir) tablets 200-50 mg	120 per 30 days	
Lexiva (fosamprenavir) suspension 50 mg/mL	1575 mL per 28 days	• Adults: 1400 mg twice daily, 1400 mg once daily with ritonavir, or 700 mg twice daily with ritonavir; 350-700 mg twice daily without ritonavir (therapy-naive) or 300-450 mg twice daily plus ritonavir once daily with moderate to severe hepatic impairment • Pediatric patients: Based on body weight (18 to 45 mg per kg), up to a maximum dose of 400 mg/100 mg twice daily
Lexiva (fosamprenavir) tablets 700 mg	120 per 30 days	
Norvir (ritonavir) capsules 100 mg	360 per 30 days	• Adults: 600 mg twice daily • Pediatric patients: Based on body surface area, up to a maximum dose of 600 mg twice daily
Norvir (ritonavir) oral solution 80 mg/mL	480 mL per 30 days	
Norvir (ritonavir) tablets 100 mg	360 per 30 days	
Norvir (ritonavir) oral powder, 100mg packet (30 per carton)	360 packets per 30 days	
Odefsey (emtricitabine 200 mg, rilpivirine 25 mg, tenofovir alafenamide 25 mg) tab	30 per 30 days	• One tablet once daily

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Medication	Standard Limit*	FDA-recommended dosing
Pifeltro (doravirine) tablets 100 mg	60 per 30 days	• One tablet once daily • Co-administration with rifabutin: one tablet twice daily
Prezcobix (darunavir 800 mg and cobicistat 150 mg) tablets	30 per 30 days	• One tablet once daily
Prezista (darunavir) tablets 150 mg	180 per 30 days	• Adults with no darunavir resistance associated substitutions: 800 mg (one 800 mg tablet or 8 mL of oral suspension) with ritonavir • Pregnancy or adults with at least one darunavir resistance associated substitution: 600 mg (one 600 mg tablet or 6 mL of oral suspension) with ritonavir twice daily • Pediatric patients: Based on body weight, not to exceed the adult dose
Prezista (darunavir) tablets 75 mg	300 per 30 days	
Prezista (darunavir) suspension 100 mg/mL	400 mL per 30 days	
Prezista (darunavir) tablets 600 mg	60 per 30 days	
Prezista (darunavir) tablets 800 mg	30 per 30 days	
Rescriptor (delavirdine mesylate) tablets 100 mg	900 per 30 days	• 400 mg three times daily • 1000 mg three times daily with rifabutin co-administration
Rescriptor (delavirdine mesylate) tablets 200 mg	450 per 30 days	
Retrovir (zidovudine) capsules 100 mg	180 per 30 days	• Adults: 300 mg twice daily; 100 mg every 6 to 8 hours with renal impairment • Pediatric patients: Based on body weight, not to exceed the adult dose
Retrovir (zidovudine) syrup 10 mg/mL	1800 mL per 30 days	
Retrovir (zidovudine) tablets 300 mg	60 per 30 days	
Reyataz (atazanavir) capsules 150 mg	30 per 30 days	• Adults: 300 mg with ritonavir once daily or 400 mg once daily • Pediatric patients: Based on body weight, not to exceed the adult dose
Reyataz (atazanavir) capsules 200 mg	60 per 30 days	
Reyataz (atazanavir) capsules 300 mg	30 per 30 days	
Reyataz (atazanavir) powder 50 mg packet	180 packets per 30 days	
Selzentry (maraviroc) tablets 25 mg	240 per 30 days	• Adults:150 mg, 300 mg or 600 mg twice daily, depending on co-administered medications • Pediatric patients: 50 mg, 75 mg, 100 mg, 150 mg or 300 mg twice daily, depending on body weight and co-administered medications
Selzentry (maraviroc) tablets 75 mg	60 per 30 days	
Selzentry (maraviroc) tablets 150 mg	60 per 30 days	
Selzentry (maraviroc) tablets 300 mg	120 per 30 days	
Selzentry (maraviroc) oral solution 20 mg/mL	1840 mL per 30 days	
Stribild (elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg, tenofovir disoproxil fumarate 300 mg) tablets	30 per 30 days	• One tablet once daily

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Medication	Standard Limit*	FDA-recommended dosing
Sustiva (efavirenz) capsules 50 mg	90 per 30 days	• Adults: 600 mg once daily; 800 mg once daily when co-administered with rifampin • Pediatric patients: 100-600 mg based on body weight
Sustiva (efavirenz) capsules 200 mg	90 per 30 days	
Sustiva (efavirenz) tablets 600mg	30 per 30 days	
Symfi (efavirenz 600mg, lamivudine 300mg and tenofovir disoproxil fumarate 300mg) tablets	30 per 30 days	• One tablet once daily
Symfi Lo (efavirenz 400mg, lamivudine 300mg and tenofovir disoproxil fumarate 300mg) tablets	30 per 30 days	• One tablet once daily
Symtuza (darunavir 800mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg)	30 per 30 days	• One tablet once daily
Temixys (lamivudine 300mg, tenovir disoproxil fumarate 300mg)	30 per 30 days	• One tablet once daily
Tivicay (dolutegravir) tablets 10 mg	60 per 30 days	• Adults: 50 mg once daily; 50 mg twice daily with certain CYP3A inducers or uridine diphosphate (UDP)-glucuronosyl transferase 1A1 (UGT1A1) • Pediatric patients weighing ≥ 30 kg: 35 mg or 50 mg once daily, based on body weight. 35 mg or 50 mg twice daily, based on body weight when co-administered with certain CYP3A inducers or uridine diphosphate (UDP)-glucuronosyl transferase 1A1 (UGT1A1)
Tivicay (dolutegravir) tablets 25 mg	60 per 30 days	
Tivicay (dolutegravir) tablets 50 mg	60 per 30 days	
Triumeq (abacavir 600 mg, dolutegravir 50 mg, lamivudine 300 mg) tablets	30 per 30 days	• One tablet once daily
Trizivir (abacavir 300 mg, lamivudine 150 mg, and zidovudine 300 mg) tablets	60 per 30 days	• One tablet twice daily
Truvada (emtricitabine and tenofovir disoproxil fumarate) tablets 100-150	30 per 30 days	• One tablet once daily • One tablet every 48 hours with renal impairment
Truvada (emtricitabine and tenofovir disoproxil fumarate) tablets 133-200	30 per 30 days	
Truvada (emtricitabine and tenofovir disoproxil fumarate) tablets 167-250	30 per 30 days	
Truvada (emtricitabine and tenofovir disoproxil fumarate) tablets 200-300	30 per 30 days	
Tybost (cobicistat) tablets 150mg	30 per 30 days	• One tablet once daily

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Medication	Standard Limit*	FDA-recommended dosing
Videx (didanosine) EC capsules 125 mg	30 per 30 days	• One capsule (125 mg, 200 mg, 250 mg, or 400 mg based on body weight and creatinine clearance) once daily
Videx (didanosine) EC capsules 200 mg	30 per 30 days	
Videx (didanosine) EC capsules 250 mg	30 per 30 days	
Videx (didanosine) EC capsules 400 mg	30 per 30 days	
Videx (didanosine) Solution 2 g/ 4 oz.	1200 mL per 30 days	• Adults: 125 mg (< 60 kg) or 200 mg (≥ 60 kg) twice daily or 250 mg (< 60 kg) or 400 mg (≥ 60 kg) once daily • Pediatric patients: 100 mg/m2 (2 weeks to 8 months old) or 120 mg/m2 (> 8 months old) twice daily
Videx (didanosine) Solution 4 g/ 8 oz.	1200 mL per 30 days	
Viracept (nelfinavir) tablets 250 mg	300 per 30 days	• Adults and adolescents:1250 mg twice daily or 750 mg three times daily • Pediatric patients < 13 years of age: 45 to 55 mg/kg twice daily or 25-35 mg/kg three times daily, up to a maximum of five 250-mg tablets twice daily or three 250-mg tablets three times daily
Viracept (nelfinavir) tablets 625 mg	120 per 30 days	
Viramune (nevirapine) suspension 50 mg/5 mL	1200 mL per 30 days	• Adults: 200 mg once daily for 14 days and then 200 mg twice daily • Pediatric patients: 150 mg/m^2 once daily for 14 days and then 150 mg/m^2 twice daily, not to exceed a total daily dose 400 mg
Viramune (nevirapine) tablets 200 mg	60 per 30 days	
Viramune (nevirapine) XR tablets 100 mg	90 per 30 days	• Adults: One 400 mg tablet once daily • Pediatric patients ≥ 6 years of age: 200 mg, 300 mg, or 400 mg once daily
Viramune (nevirapine) XR tablets 400 mg	30 per 30 days	
Viread (tenofovir disoproxil fumarate) powder 40 mg/g	240 g per 30 days	• Adults and pediatric patients 12 years of age and older: 300 mg once daily; 300 mg every 48 to 96 hours with renal impairment • Pediatric patients < 12 years of age: one tablet (150, 200, 250 or 300 mg based on body weight) or 8 mg/kg oral powder (up to a maximum of 300 mg) once daily
Viread (tenofovir disoproxil fumarate) tablets 150 mg	30 per 30 days	
Viread (tenofovir disoproxil fumarate) tablets 200 mg	30 per 30 days	
Viread (tenofovir disoproxil fumarate) tablets 250 mg	30 per 30 days	
Viread (tenofovir disoproxil fumarate) tablets 300 mg	30 per 30 days	
Zerit (stavudine) capsules 15 mg	60 per 30 days	• Adults: 15 mg, 20 mg, 30 mg or 40 mg twice daily or 15 mg or 20 mg once daily (based on body weight and creatinine clearance) • Pediatric patients: Based on body weight and age, not to exceed the adult dose
Zerit (stavudine) capsules 20 mg	60 per 30 days	
Zerit (stavudine) capsules 30 mg	60 per 30 days	
Zerit (stavudine) capsules 40 mg	60 per 30 days	
Zerit (stavudine) oral solution 1 mg/mL	2400 mL per 30 days	

Medication	Standard Limit*	FDA-recommended dosing
Ziagen (abacavir) oral solution 20 mg/mL	900 mL per 30 days	• Adults: 600 mg daily, administered as either 300 mg twice daily or 600 mg once daily; 200 mg twice daily with hepatic impairment • Pediatric patients: Based on body weight, not to exceed the adult dose
Ziagen (abacavir) tablets 300 mg	60 per 30 days	

*The initial limits may apply to the generic equivalent medications.

III. REFERENCES

1. Aptivus [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2018.
2. Atripla [package insert]. New York, NY: Bristol Myers Squibb; July 2018.
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Reference number(s)
2831-A

SPECIALTY GUIDELINE MANAGEMENT

ELZONRIS (tagraxofusp-erzs)

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
Elzonris is a CD123-directed cytotoxin for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older.

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

II. CRITERIA FOR INITIAL APPROVAL

Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
Authorization of 12 months may be granted for treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) when the patient's disease is positive for CD123 expression.

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Elzonris [package insert]. New York, NY: Stemline Therapeutics, Inc.; December 2018.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

XIIDRA
(lifitegrast)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS
Xiidra (lifitegrast ophthalmic solution) is indicated for the treatment of the signs and symptoms of dry eye disease.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:
- The requested drug is being prescribed for dry eye disease
  AND
- The patient has experienced an inadequate treatment response, intolerance or contraindication to artificial tears products

REFERENCES

1. Xiidra [package insert]. Lexington, MA: Shire US Inc.; December 2017.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed October 2018.
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4. Preferred Practice Pattern. Dry Eyes Syndrome. American Academy of Ophthalmology. September 2013.

Reference number(s)
2785-H

SPECIALTY QUANTITY LIMIT PROGRAM

Diacomit (stiripentol)

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 seizures associated with Dravet syndrome 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
Diacomit 250 mg capsule	360 per 30 days	50 mg/kg/day, administered in 2 or 3 divided doses (i.e., 16.67 mg/kg three times daily or 25 mg/kg twice daily). If the exact dosage is not achievable given the available strengths, round to the nearest possible dosage, which is usually within 50 mg to 150 mg of the recommended 50 mg/kg/day. A combination of the two Diacomit strengths can be used to achieve this dosage. The maximum recommended total dosage is 3,000 mg/day.
Diacomit 500 mg capsule	180 per 30 days	
Diacomit 250 mg powder for oral suspension	360 per 30 days	
Diacomit 500 mg powder for oral suspension	180 per 30 days	

III. REFERENCES

1. Diacomit [package insert]. Redwood City, CA: Biocodex Inc.; August 2018.

CVS caremark™

North Carolina State Health Plan
FOR TEACHERS AND STATE EMPLOYEES
A Division of the Department of State Treasurer

Dale R. Folwell, CPA
STATE TREASURER OF NORTH CAROLINA
DALE R. FOLWELL, CPA

PROPOSED QUARTERLY FORMULARY UPDATES

(Effective July 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. EPIVIR HBV, VEMLIDY, ZARXIO, ZORTRESS, BARACLUDE tablets, HEPSERA, CHORIONIC GONADOTROPIN, NOVAREL, PREGNYL, FULPHILA, GRANIX, CELLCEPT, MYFORTIC, RAPAMUNE, ASTAGRAF XL, ENVARSUS XR, ZORVOLEX, RHEUMATE, FOSTEUM, FOSTEUM PLUS, VASCULERA, FML LIQUIFILM & LACTULOSE (NDC 46600020003010), & NAPROXEN (NDC 66100060001805).

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. SAVELLA, RAPAFLO, CANASA, CARAFATE, TENORETIC, & CIALIS (2.5 and 5 mg).

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. NEULASTA, EYLEA, LUCENTIS, & V-GO.

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. ELZONRIS, DIACOMIT, UDENYCA, NIVESTYM, CIMDUO, SYMFI LO, SYMFI, ESBRIET, ALYQ, TADALAFIL, VANCOMYCIN, TECENTRIQ, PROGRAF, FEMRING, NOVOLIN, LEUCOVORIN, SPRAVATO, & XEPI.

5. UTILIZATION MANAGEMENT

a. Addition of new prior authorizations, step therapy, or quantity limits to ensure clinically appropriate usage of certain medications.
b. Policies proposed:
    i. Xiidra Policy, Specialty Quantity Limit HIV Meds & Diacomit, & Elzonris SGM.

Next Scheduled Meeting: Wednesday, August 14, 2019