HIV Medication Management

LGBTQ+ Commission – HIV Workgroup

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Washington State Health Care Authority

We Apply PA When…

- Variability in the practice community.
- Clear evidence of superior efficacy or increased harms of therapies for certain conditions, or subpopulations.
- Equally effective, less costly alternatives are available.

Also….

- We work with providers to determine what information we need in order to consider the request.

HCA's HIV Policy…

- Supports access to all recommended initial HIV treatment regimens; many regimens are available without prior authorization.
- Does not require patients established on an HIV regimen to change regimens.
- In the absence of certain clinical conditions, requires patients to begin treatment on equally effective, less costly alternative prior to starting the more costly HIV drugs.
- Provides exceptions to the policy and access to non-preferred drugs on a case by case basis (mental illness, difficulties with ADL, SUD, etc.)

Prior Authorization Requests
August 1, 2020 – November 15, 2020

Prod Name (Clm)	CONTINUATION OF TREATMENT	APPROVED	CANCELLED	DENIED	Grand Total	Percent Approved
BIKTARVY	NO	44		25	69	64%
	YES	114		2	116	98%
DELSTRIGO	YES	1			1	100%
DESCOVY	NO	50	4	34	88	57%
	YES	76	2	4	82	93%
DOVATO	NO	2			2	100%
	YES	5			5	100%
EMTRICITABINE-TENOFV (TRUVADA)	NO	1			1	100%
	YES	20			20	100%
GENVOYA	NO	1			1	100%
JULUCA	NO	1		1	2	50%
	YES	12			12	100%
NEVIRAPINE	YES	1			1	100%
RUKOBIA	NO	1			1	100%
SYMTUZA	NO	3		2	5	60%
	YES	12		1	13	92%
TEMIXYS	NO			1	1	0%
TENOFOVIR (VIREAD)	YES	1			1	100%
TRUVADA	NO	4			4	100%
	YES	8			8	100%
Grand Total		357	6	70	433	82%

Seven cases were inappropriately denied for individuals continuing on treatment. When these denials were identified, they were quickly over turned, the pharmacies were contacted to reprocess the prescription and to contact the member.

Apple Health is implementing an expedited authorization code to allow pharmacists to process claims for individuals continuing on treatment if they are new to Apple Health.

Effective December 1, 2020 for the FFS program and January 1, 2021 for the MCOs.

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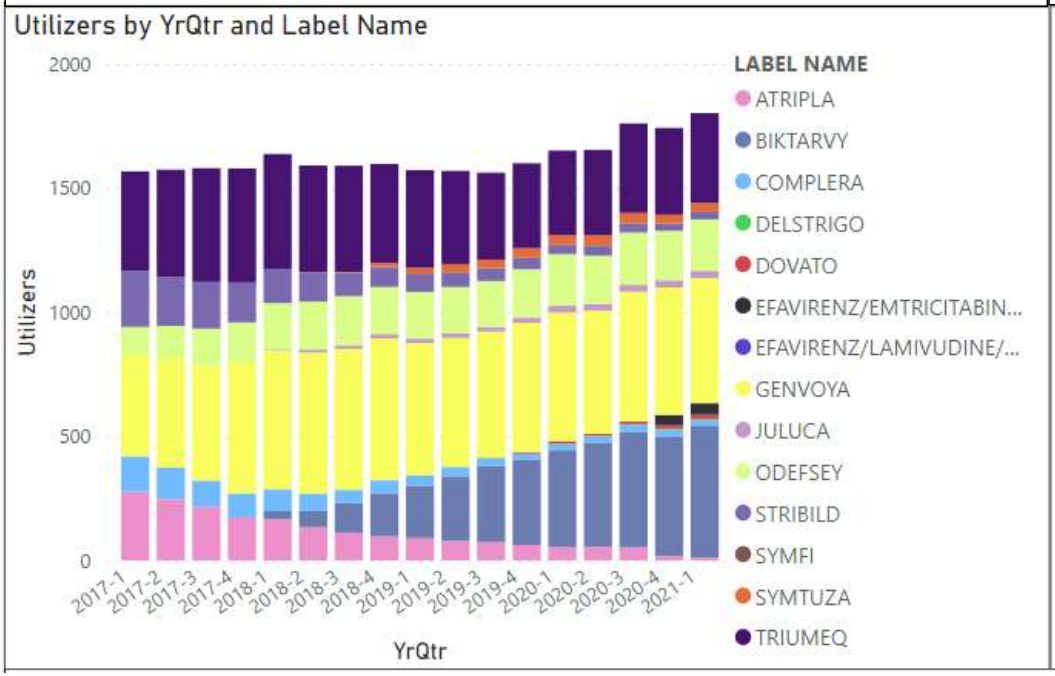
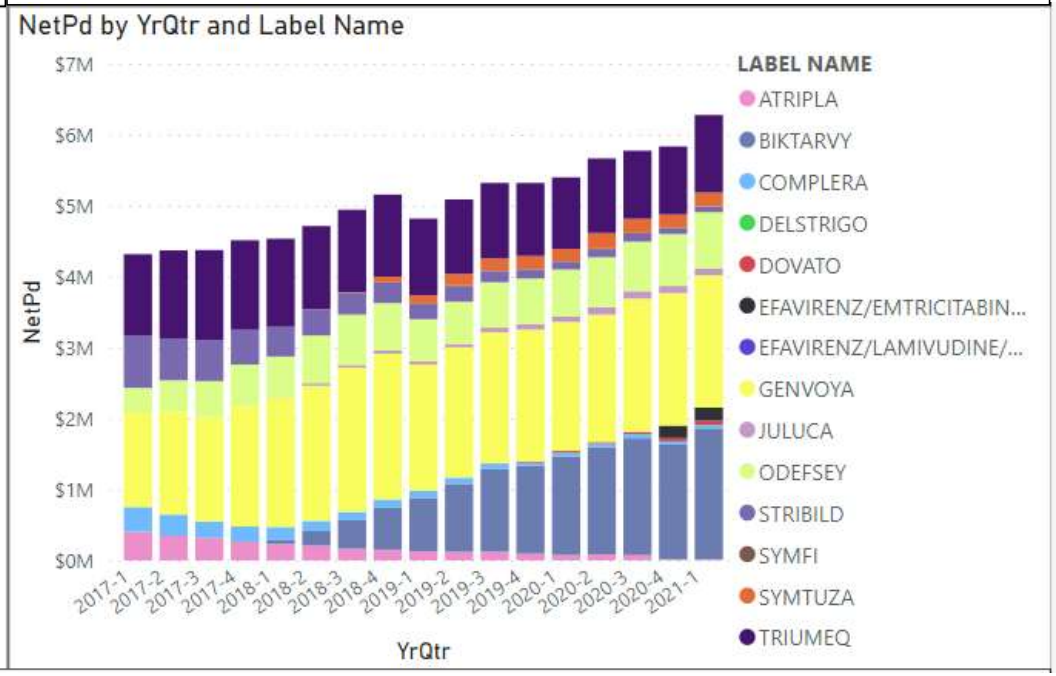
Antivirals : HIV STR Combinations - Implemented Q1 2018

Utilization for Single Tablet Regimens	Total Net Paid for Single Tablet Regimens





*Disclaimer: Data reported Q4 2020 and Q1 2021 may see a significant shift in expenses due to rebate lag. In addition, all data points may experience some degree of change after the creation of this presentation.

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What other states are doing

- 28 states have HIV medications on the PDL
  - 21 states do not prefer all HIV medications
  - 16 states have prior authorization requirements on STR
- 23 states (including DC) do not have HIV drugs on a PDL
- 11 states have legislation prohibiting management of HIV drugs
  - Most were passed in early ’90s.
  - Vermont recently repealed its prohibition
- 10 states do not have legislation but do not manage the class or prefer all products
- Utilization of STRs ranges from 10% to 91% of all HIV medications; mid-range is 65% for those states that responded.

Apple Health PDL Process

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Drug Effectiveness Review Project (DERP)

- DERP is a collaborative of 13 state Medicaid and public pharmacy programs that produces evidence-based products that assist policymakers and other decision-makers grappling with difficult drug coverage decisions.
- DERP reports include a comprehensive search of the global evidence, an objective appraisal of the quality of the studies found, and a thorough synthesis of high-quality evidence.
- Current DERP Participants
  - Colorado
  - Delaware
  - Idaho
  - Michigan
  - Minnesota
  - Missouri
  - New York
  - North Carolina
  - Oregon
  - Tennessee
  - Virginia
  - Washington
  - Wisconsin

Apple Health PDL Process

- DERP provides HCA with evidence reports, evaluating the comparative effectiveness of drugs within a class.
- Magellan provides HCA with therapeutic class reviews (TCR) which are based upon peer-reviewed practice guidelines and clinical trials.
- A summary of the DERP reports and TCRs are presented to the DUR Board.
- Stakeholders are allowed to provide public testimony on the drug class being reviewed.
- The board considers the information provided to them including, public testimony, and will form a recommendation to HCA on how to proceed to select preferred drugs.
- Magellan performs an annual financial analysis of the drug classes. This analysis incorporates Medicaid utilization data from Washington State as well as net drug costs after consideration of all rebates from manufacturers.
- After considering both DUR Board recommendations and the financial analysis from Magellan, HCA will make the final selection of preferred drugs for the PDL.

Medicaid Drug Expenditure

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Top 10 Drug Classes by Net Paid

Select the TOP number of drug classes: 40

TOP 40 % to Total Market in Net Paid: 65%

Select Period Name (*displayed as Current*): CY 2019

Select MCO/FFS: ALL

NOTE:
2019-Q4, 2020-Q1
Exclusions/Inclusi

Rank (current)	APPLE HEALTH THERAPEUTIC CLASS *Sort by Current Net Paid*	Rank (prior)	NET PAID		
			Prior	Current	% change (vs prior)
1	ANTIPSYCHOTICS / ANTIMANIC AGENTS : ANTIPSYCHOTICS - 2ND GENE..	1	$47.11M	$37.74M	-19.88%
2	ANTIVIRALS : HIV COMBINATIONS	2	$30.49M	$32.10M	5.28%
3	ADHD / ANTI-NARCOLEPSY : STIMULANTS - LONG ACTING	3	$30.20M	$29.79M	-1.37%
4	CYTOKINE AND CAM ANTAGONISTS :	4	$21.36M	$29.40M	37.63%
5	SUBSTANCE USE DISORDER : OPIOID PARTIAL AGONISTS - TRANSMUCO..	6	$15.74M	$18.43M	17.13%
6	ANTICONVULSANTS : MISC	7	$15.04M	$16.95M	12.74%
7	RESPIRATORY AGENTS : CYSTIC FIBROSIS AGENTS	9	$11.33M	$13.24M	16.87%
8	ONCOLOGY AGENTS : TYROSINE KINASE INHIBITORS - ORAL	12	$9.00M	$10.09M	12.13%
9	MULTIPLE SCLEROSIS AGENTS :	8	$13.38M	$10.03M	-25.03%
10	ANTIVIRALS : HIV	10	$9.77M	$8.87M	-9.20%

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Top 25 Drug by Net Paid

40 | 36% | CY 2019 | ALL

Rank (current)	Label Name *Sort by Current Net Paid*	Rank (prior)	NET PAID		
			Prior	Current	% change (vs prior)
1	METHYLPHENIDATE HYDROCHLORIDE ER	1	$17.27M	$15.93M	-7.78%
2	AMPHETAMINE/DEXTROAMPHETAMINE	6	$7.94M	$9.43M	18.66%
3	BUPRENORPHINE HCL/NALOXONE HCL	5	$8.10M	$7.87M	-2.87%
4	INVEGA SUSTENNA	8	$7.22M	$7.67M	6.24%
5	GENVOYA	7	$7.78M	$7.30M	-6.20%
6	ALBUTEROL SULFATE HFA	3	$9.88M	$6.81M	-31.10%
7	STELARA	13	$5.03M	$6.76M	34.38%
8	DESCOVY	11	$5.67M	$6.63M	16.99%
9	OSELTAMIVIR PHOSPHATE	23	$3.68M	$6.61M	79.63%
10	TIVICAY	12	$5.58M	$5.99M	7.25%
11	SUBOXONE	9	$6.45M	$5.53M	-14.16%
12	HUMIRA PEN	22	$3.74M	$5.31M	41.91%
13	ORKAMBI	10	$6.28M	$5.26M	-16.27%
14	COSENTYX SENSOREADY PEN	33	$2.69M	$5.13M	90.48%
15	IBRANCE	15	$4.92M	$4.88M	-0.75%
16	SYMDEKO	32	$2.72M	$4.79M	76.07%
17	TRIUMEQ	17	$4.77M	$4.25M	-10.89%
18	BUPRENORPHINE HYDROCHLORIDE/NA..	94	$0.56M	$4.24M	663.45%
19	LATUDA	16	$4.87M	$4.15M	-14.72%
20	BIKTARVY	73	$1.25M	$4.10M	227.05%
21	ARIPIPRAZOLE	4	$9.57M	$4.02M	-58.00%
22	UPTRAVI	24	$3.52M	$3.76M	6.95%
23	TECFIDERA	19	$4.31M	$3.74M	-13.11%
24	TRUVADA	21	$4.08M	$3.65M	-10.64%
25	GABAPENTIN	14	$5.03M	$3.56M	-29.09%

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Cost analysis of removing PA

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Medicaid Drug Rebate Program

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Medicaid Rebates

- Congress created the Medicaid Drug Rebate Program in 1990.
- For a drug to be covered by Medicaid, the Manufacturer must enter into National Drug Rebate agreement with the U.S. Department of Health and Human Services.
- In exchange for the rebate, Medicaid programs must cover the manufacturer's products.
- Manufacturer's must report pricing information to HHS which is used to calculate the average manufacturer's price (AMP) and the rebate amount called the unit rebate amount (URA)
- For brand name drugs, the Medicaid rebate is the greater of the AMP – 23.1% or AMP minus the manufacturers best price.
  - Best price is the lowest price paid to the manufacturer by any wholesaler, provider, retailer, HMO, government entity (excluding DOD, VA, 340B), nonprofit, or other health care purchaser.
- URAs and AMP are protected from disclosure by federal law.

Medicaid Rebate Regulations

- SEC. 1927. [42 U.S.C. 1396r–8] (a) REQUIREMENT FOR REBATE AGREEMENT.—
- (1) IN GENERAL.—In order for payment to be available under section 1903(a) or under part B of title XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of title VI of the Veterans Health Care Act of 1992[297]) and paragraph (6).

Medicaid Rebate Regulations

- Section 1927. [42 U.S.C. 1396r – 8] (a) Requirement for Rebate Agreement
- Paragraph (b)(3)(D) (D) CONFIDENTIALITY OF INFORMATION.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—
  - (i) as the Secretary determines to be necessary to carry out this section,
  - (ii) to permit the Comptroller General to review the information provided,
  - (iii) to permit the Director of the Congressional Budget Office to review the information provided,
  - (iv) to States to carry out this title;
  - (v) to the Secretary to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with subsection (f); and
  - (vi)[312] in the case of categories of drug product or classification information that were not considered confidential by the Secretary on the day before the date of the enactment of this clause.
  - The previous sentence shall also apply to information disclosed under section 1860D-2(d)(2) or 1860D-4(c)(2)(E) and drug pricing data reported under the first sentence of section 1860D-31(i)(1).

Medicaid Rebate - Examples

- Assume the AMP for a brand drug is $100 and its best price is $80.
  - The rebate is the greater of:
    - $100 x 23.1% = $23.10; or
    - $100 - $80 = $20
  - In this example the federal rebate would be $23.10
- Assume the AMP for a brand drug is $100 and its best price is $75.
  - The rebate is the greater of:
    - $100 x 23.1% = $23.10; or
    - $100 - $75 = $25
  - In this example the federal rebate would be $25.

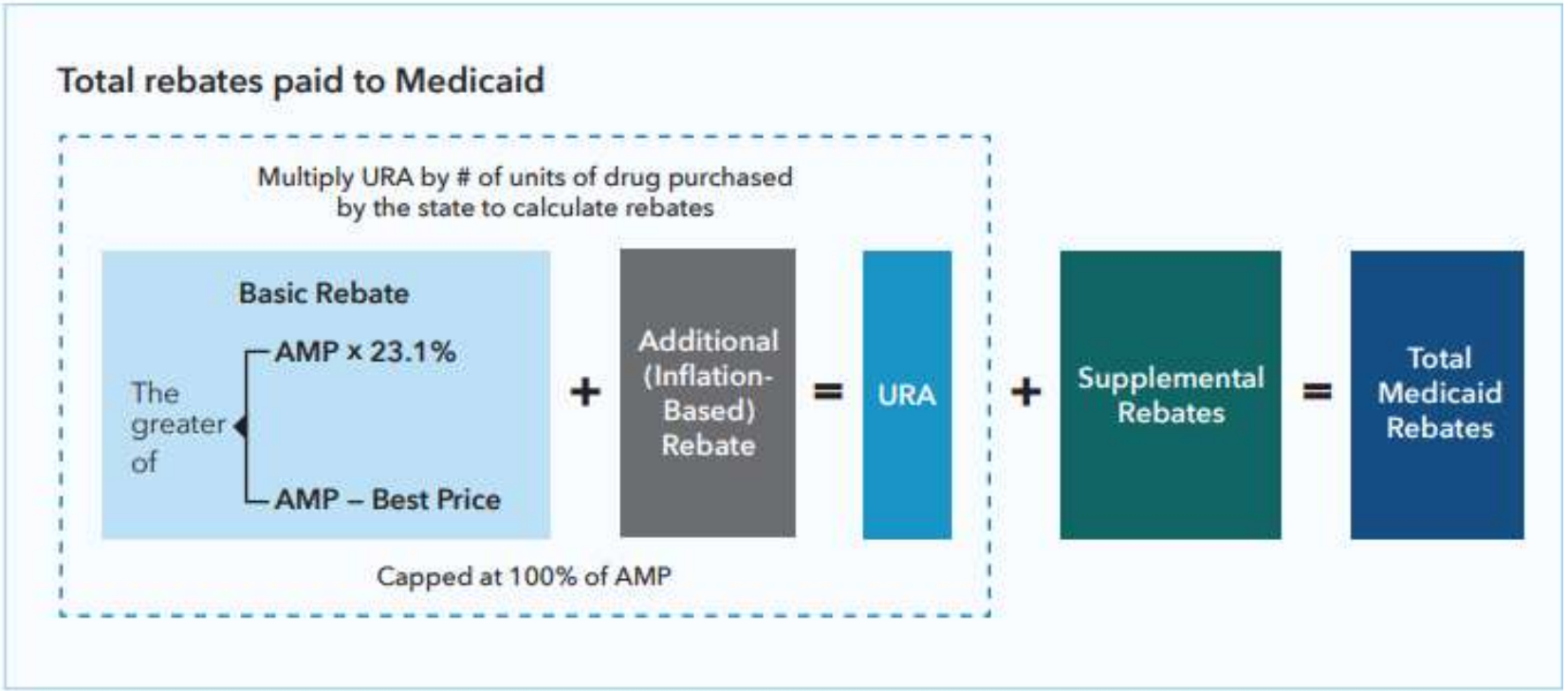
Additional Rebates

- Inflation based rebate or CPI Penalty
  - Manufacturers must pay a higher rebate when the price of the drug increases faster than the rate of inflation.
  - This additional rebate is added to the basic rebate to make up the URA for that drug.
- Supplemental Rebate Agreements (SRA)
  - Manufacturers offer Medicaid SRAs for preferential treatment on the Medicaid Preferred Drug List.

TOP$ Supplemental Rebate Pool

- Washington pays Magellan an annual fee to participates in the TOP$ supplemental rebate pool.
- Magellan negotiates SRAs agreements with manufacturers on behalf of the states participating in their program.
- Supplemental rebate agreements are renegotiated annually.
  - HIV class is renegotiated in the Spring contract cycle.
- Supplemental rebates are calculated based on a guaranteed net unit price (GNUP) offered by the manufacturer. GNUP is the net cost after federal and supplemental rebates have been applied.
  - WAC – URA – GNUP = SR
- All rebate invoices are submitted to manufacturers each quarter.
- Rebates are paid directly to the state, Washington retains 100% of the Federal and SRA received from manufacturers.

Rebate calculation - example



Relative Costs – Net of Rebate

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Questions?

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