Why HCA changed its HIV policy

Drug Utilization Review Board

December 16, 2020

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HCA mission and vision

Mission

Provide high-quality health care through innovative health policies and purchasing strategies

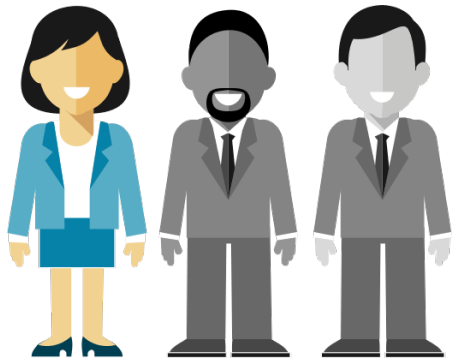
Vision

A healthier Washington

Washington State Health Care Authority

The state's largest health care purchaser

We purchase care for 1 in 3 non-Medicare Washington residents.



- We purchase health care for more than 2 million Washington residents through:
  - Apple Health (Medicaid)
  - The Public Employees Benefits Board (PEBB) Program
  - The School Employees Benefits Board (SEBB) Program

Our approach to health care purchasing

- Transforming care: better health and better care at a lower cost
- Whole-person care: integrating physical and behavioral health services
- Using data-informed evidence to make purchasing decisions

Paying for volume
(fee-for-service)

Paying for value

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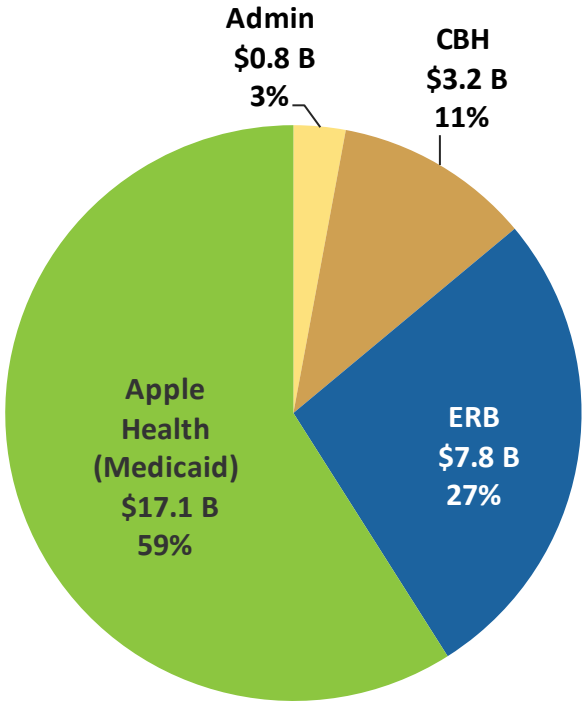
Agency budget (2019-21 biennium)

Apple Health alone Spends approximately $1 billion on prescription drugs each biennium.



Administration	$0.8 billion	3%
CBH	$3.2 billion	11%
ERB	$7.8 billion	27%
Medicaid	$17.1 billion	59%
Total Budget*	$28.9 billion	100%

Total employees (full-time equivalents): 1,428

Sources: Agency Financial Reporting System (AFRS) Allotments
** Based on 2019-21 Biennial budget ESHB 1109*
** Excludes Health Benefit Exchange $0.12 billion budget*

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Apple Health benefits

Complete major medical coverage, including:

- Appointments with a doctor or health care professional for necessary care
- Medical care in an emergency
- Maternity and newborn care and support
- Mental health services
- Kidney disease treatment
- Substance use treatment
- Pediatric services, including dental and vision care
- Limited dental and vision care for adults (**Optional)**
- Prescription medications (**Optional**)
- Laboratory services
- Hospitalization
- Transportation to and from medical appointments, when necessary
- Interpretation services

Medicaid Regulations

- HCA is the designated single state Medicaid agency and is required under Federal law to be the sole decision maker in administering the program.
- Federal dollars can only be used to pay for care deemed medicallynecessary. This may be managed through utilization review programs including prior authorization and program integrity functions.
  - **"Medically necessary"** is a term for describing requested service which is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent worsening of conditions in the client that endanger life, or cause suffering or pain, or result in an illness or infirmity, or threaten to cause or aggravate a handicap, or cause physical deformity or malfunction. **There is no other equally effective, more conservative or substantially less costly course of treatment available or suitable for the client requesting the service.** For the purposes of this section, "course of treatment" may include mere observation or, where appropriate, no medical treatment at all.

RCW 70.14.050
Drug Purchasing Cost Controls

- Each agency… shall in cooperation with other agencies, take any necessary actions to control costs without reducing the quality of care when reimbursing for prescription drugs.
- Agencies may establish an evidence-based prescription drug program.
- In developing the evidence based prescription drug program, agencies:
  - Shall prohibit [paying] for drugs that are determined to be ineffective by the US Food and Drug Administration
  - …Ensure less expensive generic drugs will be substituted for brand name drugs
  - May take other necessary measures to control cost of drugs without reducing the quality of care

Single PDL Budget Proviso - 2017

- HCA shall develop and implement single, standard Medicaid preferred drug list (PDL):
  - To be used by all contracted Medicaid managed care systems (MCO) — on or before January 1, 2018
  - In consultation with all Medicaid managed health care systems (MCO), and the Pharmacy and Therapeutics Committee or Drug Utilization Review Board
  - That ensures access to clinically effective and appropriate drug therapies, while maximizing federal and supplemental rebates
- HCA may use consultants with expertise in evidence-based drug class reviews, pharmacy benefit management, and purchasing

Preferred Drug Lists

- In 2003 the legislature directed HCA to create an independent Pharmacy and Therapeutics committee to evaluate the effectiveness of prescription drugs in the development of the evidence-based prescription drug program.
- In 2017 the legislature directed HCA to create a single preferred drug list for the Apple Health program beginning 2018.
- HCA has over 15 years managing a preferred drug list for state agencies.
  - We have successfully managed many drug classes for serious chronic diseases such as Antidepressants, Atypical Antipsychotics, Multiple Sclerosis, and other Auto-Immune disorders on the PDL without harm to patients.
  - HCA treats HIV like any other serious chronic disease.

Why Does HCA apply Prior Authorization?

- HCA is obligated to be good stewards of the resources entrusted to us.
  - We receive a significant amount of the state budget to provide health care benefits to one third of Washington non-Medicare covered residents
  - We need to use limited state dollars wisely, especially when there is an economic downturn like we are in currently, to maintain optional benefit programs including adult dental services which has been cut in the past.
- Prior authorization is resource intensive for both plans and providers, however not having prior authorization leads to increased expenses.
- Prior authorization allows HCA to review services or prescriptions and includes looking for any potentially dangerous drug interactions that prescribers may have been unaware of when prescribing and prevent unneeded medications from being prescribed.

Prior Authorization Requirements

- Requirements are developed to assure that only safe and effective treatment is provided.
- Medical intervention starts with what is accepted to be equally effective and less costly.
  - Since each payer has their own unique payment structure, the least costly alternative may be different for each payer.
  - It is after the failure of less costly treatment alternatives that patients receive other and, often, more costly treatment.
- Typically, the less costly alternative works for most patients and does not require PA.
- Exceptions are made on a case by case basis.
- This approach is to the benefit of the patient, the employer or program and all other covered lives.

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.

Antivirals : HIV - Implemented Q1 2018

- Stable utilization, but higher costs
  - Utilization of top HIV expenses show Biktarvy, Genvoya, Tivicay, and Descovy as significant contributors to the trending increase in Net Paid PMPM
  - Indicates a shift in prescribing patterns to significantly more expensive therapies

YrQtr	NetPd PMPM	NetPd/Clm	DS PMPM	Claims	Utilizers
2017_1	$2.49	$992.52	0.07	14,440	6036
2017_2	$2.61	$1,020.38	0.08	14,678	6106
2017_3	$2.67	$1,052.16	0.07	14,352	5940
2017_4	$2.76	$1,077.87	0.08	14,441	6057
2018_1	$2.90	$1,108.22	0.08	14,743	6372
2018_2	$2.96	$1,130.80	0.08	14,613	6205
2018_3	$3.03	$1,162.58	0.08	14,490	6136
2018_4	$3.11	$1,175.07	0.08	14,658	6100
2019_1	$3.02	$1,193.26	0.07	13,927	6092
2019_2	$3.21	$1,204.24	0.08	14,549	6075
2019_3	$3.26	$1,221.09	0.08	14,574	6046
2019_4	$3.23	$1,224.53	0.08	14,442	6007

*Disclaimer: Data reported Q3 and Q4 2019 are incomplete 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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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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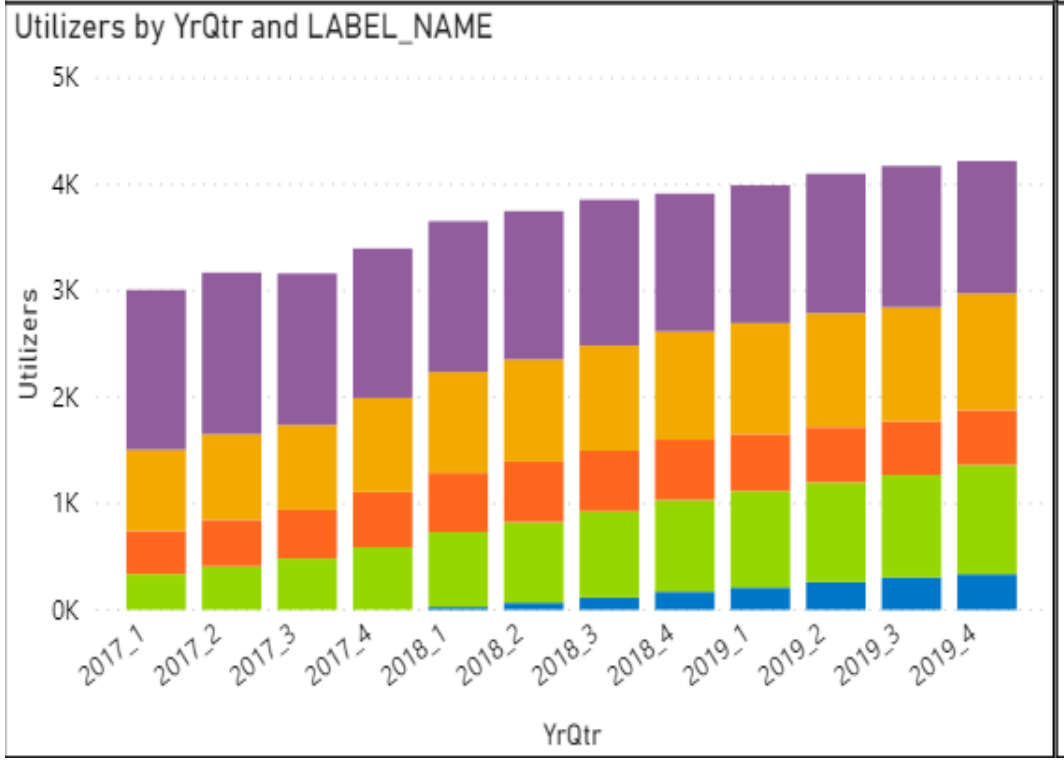
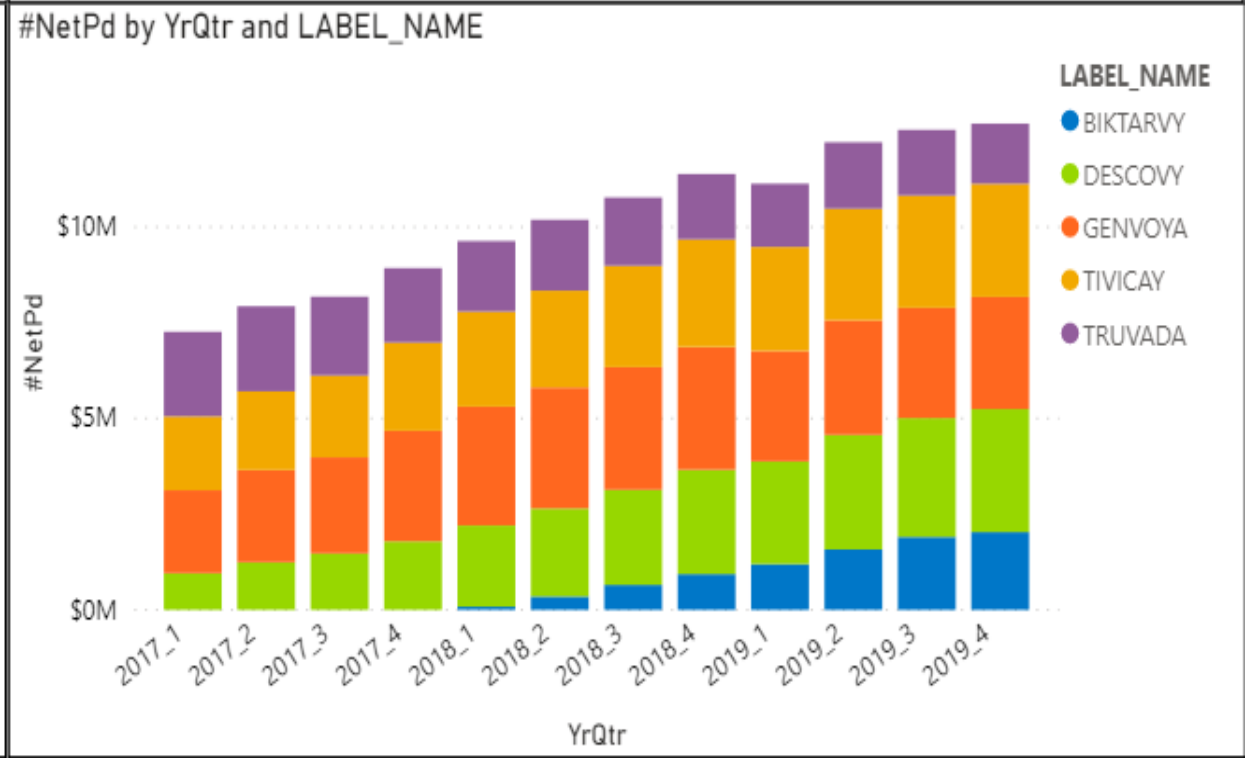
Antivirals : HIV - Implemented Q1 2018

Total Utilizers for Top 5 Label Names with Highest Cost



Total Net Paid for Top 5 Label Names



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Top 10 Drug Classes by Net Paid

- **5, 955 unique individuals received at least one prescription for an HIV medication**
- **HCA spends more on HIV medications than any other drug class (over $40 million annually)**

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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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%

In 2019 **6** of the top **25** drugs by net expenditure were HIV medications, treating 5,195 unique individuals, equaling $32 million.

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Are Single Tablet Regimens Better?

"Biktarvy was found to be no worse than Tivicay + Descovy"

Coformulated bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir with emtricitabine and tenofovir alafenamide, for initial treatment of HIV-1 infection (GS-US-380-1490): a randomised, double-blind, multicentre, phase 3, non-inferiority trial

Paul E Sax, Anton Pozniak, M Luisa Montes, Ellen Koenig, Edwin DeJesus, Hans-Jürgen Stellbrink, Andrea Antinori, Kimberly Workowski, Jihad Slim, Jacques Reynes, Will Garner, Joseph Custodio, Kirsten White, Devi SenGupta, Andrew Cheng, Erin Quirk

Implications of all the available evidence

Results from this study showed non-inferiority of bictegravir, emtricitabine, and tenofovir alafenamide fixed-dose combination versus dolutegravir plus emtricitabine and tenofovir alafenamide. Coformulated bictegravir, emtricitabine, and tenofovir alafenamide is a once a day, potent, unboosted INSTI-based regimen that is expected to have virological activity similar to dolutegravir administered with two NRTIs and has a low likelihood of inducing resistance.

www.thelancet.com Vol 390 November 4, 2017

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Is TAF safer than TDF?

Journal of Virus Eradication 2018; **4**: 215–224

ORIGINAL RESEARCH

How safe is TDF/FTC as PrEP? A systematic review and meta-analysis of the risk of adverse events in 13 randomised trials of PrEP

Victoria Pilkington[1], Andrew Hill[2]*, Sophie Hughes[3], Nneka Nwokolo[4] and Anton Pozniak[4,5]

[1]Faculty of Medicine, Imperial College London, London, UK
[2]Department of Pharmacology and Therapeutics, University of Liverpool, UK
[3]MetaVirology Ltd Research, London UK
[4]Chelsea and Westminster Hospital, 56 Dean Street, London UK
[5]London School of Hygiene and Tropical Medicine, London UK

Is TAF-FTC safer than TDF-FTC for PrEP? When used as part of multidrug regimens for HIV treatment, TDF can cause renal or bone adverse events (5, 6), whereas TAF is associated with weight gain and changes in lipid parameters (7), although serious harms are rare. However, a decade's worth of research has demonstrated the excellent safety of TDF-FTC used as PrEP. A systematic review of TDF-FTC or TDF alone used as PrEP by thousands of trial participants found no differences in renal or bone harms compared with placebo or no treatment (8). It is also reassuring that more than 200 000 U.S. patients have been prescribed TDF-FTC PrEP and no serious toxicities have been reported.

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Is TAF safer than TDF?

There were 12 cases of grade 3+ serum creatinine elevation, used as a surrogate marker for renal impairment, occurring across the trials. On meta-analysis (Figure 4), there was no significant difference (P=0.68) between numbers of events in treatment versus control trial arms. The overall risk difference was 0.00 (95% CI –0.00 to 0.00). Statistical tests revealed no heterogeneity (I^2=0%). Subgroup analyses demonstrated no further statistically significant differences, and there was no statistical difference between subgroups, (I^2=0%, P=0.65), indicating a consistent rate of adverse events over time.

Severity of Creatinine Elevations

Grade 1 = 1.1 – 1.3 times the upper limit
Grade 2 = 1.1 – 1.8 times the upper limit
Grade 3+ > 1.9 times the upper limit

Given the low numbers of grade 3+ creatinine elevations occurring, a further analysis of creatinine elevations of all grades (1–4) was undertaken. A total of 514 creatinine elevations occurred (97.7% being grades 1–2). Grade 1 is defined as 1.1–1.3 times the upper limit of the normal range (ULN) and grade 2 is 1.1-1.8 x ULN, while grade 3+ is >1.9xULN. On meta-analysis (Figure 5), there was a borderline statistically significant overall risk difference (P=0.04) between numbers of events in treatment versus control arms. The overall risk difference was 0.02 (95% CI 0.00–0.03). Statistical tests revealed substantial heterogeneity (I^2=93%). Subgroup analyses demonstrated no further statistically significant differences, and there was no statistical difference between subgroups, (I^2=0%, P=0.48), indicating a consistent rate of adverse events over time.

Pilkington,et al. Journal of Virus Eradication 2018; 4: 215 -225.

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Tough Decisions

- Most patients can successfully achieve and maintain viral suppression with the preferred, once daily, multi-pill regimens listed on the Apple Health Preferred Drug List.
- Recently FDA-approved drugs offer convenience through once-daily single-tablet dosing but are no more effective or safe and cost much more when formulated as a combination drug than the individual components.
- Critically needed state supported optional Medicaid programs such as the adult dental program have been defunded in the past during economic downturns.
- HCA is responsible for the stewardship of scarce resources and protecting essential services for the entire safety net.
- Are the higher priced single tablet regimens that are no better than the multi-tablet regimens or the TAF containing products that also have serious side effects worth it?

Questions?

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