Impact of Screening Criteria for Tenofovir Alafenamide Eligibility in the BC Centre for Excellence in HIV/AIDS (BC-CfE) Drug Treatment Program (DTP)

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Conflict of Interest Disclosure

Dr. Marianne Harris

In the past 2 years I have been an employee of: **None**

In the past 2 years I have been a consultant for: **Gilead Sciences Canada Inc., Merck Canada Inc., ViiV Healthcare**

In the past 2 years I have held investments in the following pharmaceutical organizations, medical devices companies or communications firms: **None**

In the past 2 years I have been a member of the Scientific advisory board for: **Gilead Sciences Canada Inc., Merck Canada Inc., ViiV Healthcare**

In the past 2 years I have been a speaker for: **Gilead Sciences Canada Inc., Merck Canada Inc., ViiV Healthcare**

In the past 2 years I have received research support (grants) from: **None**

In the past 2 years I have received honoraria from: **Gilead Sciences Canada Inc., Merck Canada Inc., ViiV Healthcare**

I agree to disclose approved and non-approved indications for medications in this presentation: **YES**

I agree to use generic names of medications in this presentation: **YES**

There are relationships to disclose: **YES**

Background

- Tenofovir alafenamide (TAF)-containing products were added to the BC-CfE formulary:
  - emtricitabine/TAF (Descovy®) in March 2017
  - elvitegravir/cobicistat/emtricitabine/TAF (Genvoya®) in July 2017
- Due to the availability of generic products, regimens including tenofovir DF (TDF) or abacavir were considerably less expensive than regimens containing TAF. In March 2017, 3981 (56%) of 7134 DTP participants were receiving TDF and 2824 (40%) were receiving abacavir.
- Considering cost issues, in March 2017 the BC-CfE DTP implemented clinical criteria to reserve TAF for persons with medical need.
- TAF eligibility was assessed during the routine review and approval process applied to all antiretroviral prescriptions received by the BC-CfE DTP.
- We evaluated TAF prescription requests, and the impact of the criteria on TAF usage in the province.

Methods

- Data were extracted from the BC-CfE DTP database for all participants for whom a TAF prescription request was received and reviewed for approval between March 1, 2017 and May 30, 2018.
- TAF eligibility criteria were ≥1 qualifying medical issue (renal or bone health) precluding TDF use AND ≥1 qualifying reason to not use abacavir.

TAF criteria	Meets BC-CfE TAF criteria	Does not meet BC-CfE TAF criteria
Reason why abacavir cannot be used	HLA-B*5701 positive Genotypic resistance compromising abacavir activity Documented adverse drug reaction or intolerance to abacavir Hepatitis B coinfection	Refuses to take abacavir Concerns about cardiovascular risk Any other reason, or no reason provided why abacavir is not an option
Renal Health	eGFR ≥30 to 59 mL/min[1] Severe hypophosphatemia: Serum phosphate < 0.32 mmol/L	eGFR ≥60 or <30 mL/min[1] Serum phosphate ≥0.32 mmol/L Proteinuria Any other reason related to renal health
Bone Health	Osteoporosis: T-score ≤ -2.5 Fragility fracture(s)	T-score >-2.4 Other bone-related reason, including low bone mass or osteoporosis without a T-score
Other	Not applicable	Other reason (not renal or bone health) or no reason provided

eGFR, estimated glomerular filtration rate

1. TAF is not recommended in patients with eGFR <30 mL/min [Gilead Sciences Canada Inc. Descovy® (emtricitabine/ tenofovir alafenamide tablets) Product Monograph. September 23, 2019.]

Results

Of 324 TAF requests, 281 (87%) were approved, of which 163 (58%) met and 88 (31%) partially met TAF criteria. None of the 43 (13%) non-approved requests met TAF criteria.

	TAF Approved, met all criteria	TAF Approved, met abacavir non-use but not medical criteria	TAF Approved, met medical but not abacavir non-use criteria	TAF Approved, no criteria met	TAF Not Approved
N	**163**	**76**	**12**	**30**	**43**
Abacavir non-use criteria met	**163 (100%)**	**76 (100%)**	**0**	**0**	**16 (37%)**
Renal criteria met	**100 (61%)**	**0**	**10 (83%)**	**0**	**8 (19%)**
Bone criteria met	**53 (33%)**	**0**	**2 (17%)**	**0**	**3 (7%)**
Renal and bone criteria met	**10 (6%)**	**0**	**0**	**0**	**1 (2%)**
Other renal reasons[1]	**NA**	**21 (28%)**	**NA**	**3 (10%)**	**6 (14%)**
Other bone reasons[2]	**NA**	**25 (33%)**	**NA**	**1 (3%)**	**3 (7%)**
Other renal + other bone reasons[1,2]	**NA**	**15 (20%)**	**NA**	**1 (3%)**	**3 (7%)**
Other medical reasons(s)	**NA**	**10 (13%)**	**NA**	**21 (70%)**	**2 (5%)**

Total N=324; data shown are approval category N (column %). TAF: tenofovir alafenamide. Medical criteria: ≥1 renal or bone health- related reason why tenofovir DF is not an option; abacavir non-use criteria: ≥1 reason why abacavir is not an option. NA, not applicable.

1. eGFR ≥ 60 mL/min but declining; proteinuria; mild to moderate hypophosphatemia
2. Low bone density, T-score -1.0 to -2.4

Conclusions

- Starting in March 2017, the BC-CfE provided TAF to DTP participants with a valid medical reason not to be treated with less costly generic alternatives.
- During the first 15 months that TAF eligibility criteria were applied, 87% of TAF requests received by the DTP were approved.
- In April 2019, 89% of 7386 DTP participants were receiving TDF or abacavir (mainly as generic products), while 8% were receiving TAF.
  - TDF: n=3260 (44%)
  - Abacavir: n=3291 (45%)
  - TAF: n=587 (8%)
- The application of medical eligibility criteria moderated the use of TAF in BC, while cost savings from generic antiretrovirals were maintained.