Centers for Medicare and Medicaid Services (CMS) (ICR Form):
Public Submission Form for Information about Selected Drugs and Their Therapeutic Alternatives

Public Submission Form for Information about Selected Drugs and Their Therapeutic Alternatives
Selected Drug: BIKTARVY

Form submitted on February 27, 2026, by Marcus J. Hopkins, Health Policy Lead Consultant, on behalf of the ADAP Advocacy Association.

- CMS has grouped Questions 28 through 54 into five topic categories addressed by the set of questions. Specifically, these categories by question number are:
    - Questions 28-33: Patient- or Caregiver-Focused Input
    - Questions 34-39: Manufacturer-Focused Input
    - Questions 40-45: Clinical-Focused Input
    - Questions 46-51: Health Research-Focused Input
    - Questions 52-54: Other Public Input

I27: Question 27: Respondent Information

Individuals or organizations, including manufacturers, that wish to provide information in this

Section I must provide the following information.

Are you or your organization affiliated with the manufacturer of the selected drug or its potential therapeutic alternative(s)? *

Yes
No

I28_33: Questions 28 through 33: Patient-Focused Experience

CMS would like your input to better understand patients' and caregivers' experiences with the selected drug. In this section, CMS is interested in your experience with the selected drug, the health condition(s) that the selected drug may be used to treat, and other medications that may be used to manage those condition(s). Individual patients and caregivers, and organizations representing patients and/or caregivers are encouraged to answer the following.

I28: Question 28: Background

Question 28a: Have you or someone you provide care for ever taken the selected drug?

Yes
No

I29: Question 29: Information on Your Condition(s) or Condition(s) of Someone You Care For

Question 29a: How do the condition(s) you listed in Question 28a1 impact your daily life and well-being or the daily life and well-being of someone you provide care for?

For example,
What are your symptoms related to the condition(s) on a "good" or "bad" day?
How do these symptoms impact daily routines, work, family, and/or hobbies?
What other activities are impacted by your symptoms?

Response to Question 29a
1400/36000 characters

Since being diagnosed with HIV in 2005, I have experienced the following side effects:

- Decreased levels of energy
- Increased gastrointestinal issues, including vomiting and diarrhea
- Greater susceptibility to multiple types of opportunistic infections and parasites, including Giardia, Norovirus, Cryptosporidium, Influenza, Pneumonia, Respiratory Syncytial Virus (RSV), and other respiratory ailments
- Longer periods of illness after contracting opportunistic infections

On a “good” day, I can function relatively normally, in no small part because of medications like Biktarvy, which have allowed me to control my virus and improve my quality of life.

On a “bad” day, none of that occurs. I have been forced to miss work, lose income, lose jobs, miss classes, have my grades suffer, and be considered unreliable by friends, co-workers, and colleagues.

Where once I was a highly skilled and well-regarded performer in the performing arts, the HIV virus and its progression to an AIDS diagnosis destroyed much of my credibility as I became less and less able to meet the basic requirements of physical endurance.

When I first began treatment for my HIV in 2007, the side effects of the medications I was prescribed often tethered me to a single location, making travel difficult as I was required to carry a lunchbox with me at all times containing an ice pack to keep my medications at the correct temperature.

Question 29b: How has the condition(s) you listed in Question 28 changed or progressed over time?

For example,
Have you, or someone you provide care for, experienced changes in severity of the condition(s)?

Have you, or someone you provide care for, experienced changes in how often you feel symptoms?

Response to Question 29b
885/36000 characters

After being diagnosed with HIV in 2005, I received an AIDS designation on October 19th, 2007. As the severity of my disease worsened, so too did my quality of life decrease. Simple colds became week-long events.

Even after I began treatment and achieved viral suppression and undetectability, my capabilities have been, to some degree, limited by my ability to maintain my energy levels for an entire day, to manage medication-related side effects, and to recover in a timely manner from opportunistic infections.

As medications have improved over time, with newer single-tablet regimens offering fewer side effects, side effect management has improved to some degree, as has my ability to travel. Realistically, though things have improved, the long-term impacts of the disease have resulted in some negative side effects, even though my virus is successfully suppressed and controlled.

[RESPONSE HERE]

Question 29c: What is important to you or those you provide care for in managing the condition(s) you listed in Question 28?

This may be how you feel or function in your daily life, how long you live, or other goals you have related to your medication(s) or condition(s).
For example, this could mean fewer symptoms, better ability to complete daily tasks such as chores, fewer visits to your doctor or hospital, fewer side effects, lower health care costs, worrying less about your health, or other things.

Response to Question 29c
1648/36000 characters

What has fundamentally changed for people living with HIV/AIDS is the survivability and manageability of the disease and its symptoms. As medications have improved over the past forty years, from AZT to single-pill and long-acting injectable treatment options, HIV/AIDS has progressed from being a death sentence in the 1980s to being something easily managed with more easily tolerated medications.

I have progressed from monthly visits to bi-monthly visits and now see my HIV specialist once or twice a year.

Healthcare costs, however, remain significant. Aside from the costs of the medications used to treat HIV, there are other costs I have to navigate to address my condition. Despite having insurance coverage, I've had to fight with my insurers multiple times to cover the cost of blood

tests, provider visits, and hospital visits, even though the plan I selected specifically states that these services are covered.

As I get older, the long-term impacts of living with HIV/AIDS manifest in other ways, as well: at 43, I started to experience early signs of geriatric syndromes, including physical frailty, falling, and occasional cognitive impairment (presenting as "losing words," when, despite having sufficient experience, education, and knowledge, I am unable to find and use words with which I'm very familiar while speaking). I've also experiencing chronic joint inflammation and higher susceptibility to food-borne illnesses.

I've spent much of the past year attempting to figure out why my legs will occasionally just "stop" working, leading to significant and dangerous falls, and I am now walking full-time with a cane for stability.

[RESPONSE HERE]

Question 29d: What challenges do you, or someone you care for, face in managing this condition(s)?

Response to Question 29d
1809/36000 characters

One of the most difficult aspects of managing HIV/AIDS for me has been attempting to obtain, maintain, and afford the cost of care and treatment. On numerous occasions, health insurance representatives have recommended "alternative" treatment options for medications to treat the condition that are no longer being actively prescribed.

As an example, despite having health insurance and being on Genvoya for a number of years, my claim was denied after they changed the formulary to exclude Genvoya, with Atripla being recommended as an alternative. At that time, Atripla had not been actively prescribed for several years, and side effects for the medication were notoriously difficult to tolerate and maintain a normal lifestyle.

As with most chronic illnesses, the long-term financial impacts have been significant. I've had to take out credit cards and borrow money from friends on numerous occasions to afford medications or provider visits. I have been hospitalized several times for opportunistic infections and conditions, including influenza, pneumonia, and severe gastrointestinal issues, that have cost me well over $200,000 over the past 20 years since I was diagnosed.

Over the past year, I have required assistance even getting *to* a healthcare provider to address emergent health issues, as I was essentially incapacitated and unable to physically get to my personal vehicle, much less safely drive it to and from either urgent or emergency care providers.

Financial issues related to my chronic illness necessitated borrowing several thousand dollars from multiple friends and family members, as well as the selling of many treasured possessions in order to afford basic necessities that were delayed due to medical costs, including funds to pay for housing, utilities, and other required services.

[RESPONSE HERE]

I30: Question 30: Information on the Current Medication to Treat Your Condition
Question 30a: Are you, or someone you care for, currently taking medication(s) to manage the condition(s) you listed in Question 28?

Yes
No

Question 30a1: What medication(s) are you, or someone you provide care for, currently taking to manage the condition(s) you listed in Question 28?

Cabenuva (cabotegravir; rilpivirine)

Question 30a2: How did you or someone you care for decide to start taking the medication(s) currently used to manage the condition(s) you listed in Question 28?

What factors, if any, affected the choice of medication(s) currently used to manage the condition(s) you have selected? For example, this could mean side effects, cost, interactions with other medication, whether your local pharmacy or mail-order pharmacy could provide it, family influence, interference with your work or life, other health condition(s), whether the medication was covered by your insurance, whether your medical provider recommended the medication based on clinical guidelines or clinical experience, or other things that influenced your choice.

The decision to transition from Biktarvy to Cabenuva was made after nearly a decade of taking Biktarvy due to my consistent medication adherence, sustained virologic suppression, and eligibility to begin long-acting injectable treatments.

Question 30a3: What has been your experience, or the experience of someone you provide care for, with the medication(s) currently used to manage the condition(s) you listed in Question 28?

What are benefits of the medication(s)? What do you like about it?
What are drawbacks of the medication(s)? What do you wish was different?
How do the medication(s) impact daily life? Does the medication(s) make you feel better in your daily life?
How easy or difficult is it to take the medication(s)? What is difficult about taking your medication(s)?
Has taking this medication impacted your emotional or mental well-being? How?

Benefits:

The primary benefit of switching from Biktarvy to bi-monthly long-acting injections with Cabenuva has been the ease of transition. Not having to worry about taking daily medications has been a significant change in my life, and I no longer feel tethered to my home.

Question 30a4: How satisfied are you, or someone you care for, with the medication(s) you take now to manage your condition(s)?

I am very satisfied.

I31: Question 31: Information on the Medication(s) Used in the Past to Treat Your Condition

Question 31a: Have you, or someone you care for, taken other medication(s) in the past to manage the condition(s) you listed in Question 28?

Yes
No

Question 31b1: What medication(s) have you, or someone you care for, taken in the past to manage the condition(s) you listed in Question 28?
If possible, please indicate when past medication(s) were started and stopped to the best of your knowledge.

Lexiva (Fosamprenavir) - Taken from 2007-2012
Truvada (Emtricitabine/tenofovir disoproxil fumarate) - Taken from 2007-2012
Norvir (Ritonavir) - Taken from 2007-2010
Reyataz (Atazanavir) - Taken from 2010-2012
Stribild (Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate) - Taken from 2013-2015
Genvoya (Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide) - Taken from 2015-2018
Biktarvy (Bictegravir/emtricitabine/tenofovir alafenamide) - Taken from 2018-2025

Question 31b2: How did you, or someone you care for, decide to start taking the medication(s) used in the past to manage the condition(s) you listed in Question 28?
What other factors, if any, affected the choice of medication(s) used in the past to manage the condition(s) you listed in Question 28?
For example, factors could include side effects, cost, interactions with other medication, whether your local pharmacy or mail order pharmacy could provide it, family influence, interference with your work or life, other health condition(s), whether the medication was covered by your insurance, whether your medical provider recommended the medication based on clinical guidelines or clinical experience, or other things that influenced your choice.

Medications were updated and changed in consultation with my HIV care physicians based on improving virologic suppression, increasing CD4 levels, and the reduction of medication-related side effects.

Changes were made as newer drugs became available and the standards of care changed and improved.

Question 31b3: What was your experience, or the experience of someone you provide care for, with the medication(s) used in the past to manage the condition(s) you listed in Question 28?
What are benefits of the medication(s)? What do you like about it?
What are drawbacks of the medication(s)? What do you wish was different?
How do the medication(s) impact daily life? Does the medication(s) make you feel better in your daily life?
How easy or difficult is it to take the medication(s)? What is difficult about taking your medication(s)?
Has taking this medication impacted your emotional or mental well-being? How?

The primary drawback related to Lexiva was the requirement in early formulations to keep the medication refrigerated to maintain its efficacy.

The primary drawback of multi-pill regimens was the requirements to keep track of multiple medications and ensure accurate daily dosing.

Question 31b4: Why did you, or someone you provide care for, stop taking the medication(s) used in the past to manage the condition(s) you listed in Question 28?

Medications were not halted; I simply transitioned to newer, more effective, and more easily tolerated regimens.

I32: Question 32: What other information about the condition(s) you have identified or the medication(s) used to manage these condition(s) do you think CMS should consider while evaluating the selected drug?

Response to Question 32
3098/36000 characters

I was first diagnosed with HIV on April 12th, 2005, in Atlanta, GA, at the AID Atlanta location in Midtown. At the time, treatment protocols in the United States were such that HIV treatments were not prescribed to patients living with HIV until they had received an AIDS diagnosis, which I received on October 19th, 2007, in Ft. Lauderdale, FL.

My first treatment regimen was a three-pill combination of Lexiva, Norvir, and Truvada, the first of which required constant refrigeration, which made travel difficult.

In addition to storage issues, the side effects were life-altering. I went from being able to function during the day to worrying whether I could make it to the bathroom in time while at work. I went from being an elite-level performer in the performing arts to being unable to perform for more than 5 consecutive minutes without needing to take a break to vomit.

I remained on a multi-pill regimen from 2007 to 2013, when I was offered the opportunity to transition to a single-pill regimen—Stribild.

This new regimen allowed me, for the first time in nearly six years, to not carry a lunchbox containing an ice pack to keep my medications at the right temperature. It allowed me the freedom to live life as normally as possible.

Beyond the convenience, the side effects were considerably less noticeable. I was able to live a relatively normal life, with only occasional moments of physical exhaustion that left me unable to go to work, school, or leave my home.

Over the next 12 years, I continued to upgrade to newer, better treatment options. I went from Stribild to Genvoya, and from Genvoya to Biktarvy—a regimen that served me well for nearly a decade.

On Biktarvy, I was finally able to live a mostly normal life. After beginning Biktarvy, I noticed a considerable decrease in side effects; I was able to effectively control my HIV/AIDS and improve both my CD4 count and decrease my viral load beyond just being virally suppressed to being undetectable.

Biktarvy gave me my life back, and without having access to the drug, I might still be relying upon regimens that had side effects that were difficult to manage.

I am just one of hundreds of thousands of success stories.

Biktarvy is *the* most commonly prescribed treatment regimen for HIV, with over 430,000—roughly 35.8%—of people living with HIV/AIDS in the United States relying upon the medication to control their HIV[1].

In 2025, ADAP Advocacy requested a carve-out exemption from the Medicare Drug Price Negotiation Program for HIV medications, specifically because of the risk that manufacturers, rather than accept significant financial losses, would simply opt to remove their medications from Medicare coverage.

The prospect of losing access to HIV medications paid for through Medicare poses a significant risk to PLWHA. Medicare is the 2nd-largest payor of HIV treatment and care in the United States, accounting for 39% of federal spending in 2020, and serving 28% of PLWHA. Additionally, 77% of PLWHA who are enrolled in Medicare first qualified for the program not because of age but because of a disability diagnosis[2].

[RESPONSE HERE]

I33: Question 33: Demographic Questions [Only when a respondent selects the "patient" or "caregiver" option in response to Question 27.]

To put the above responses into context, CMS is interested in understanding the demographic information of the individual who has used the selected drug:

Age

44

Regional Location

Mid-Atlantic Region

Medicare Beneficiary

Yes

No

I52_54: Questions 52 through 54: Other Public Input

CMS is collecting information to support its evaluation of selected drug relative to potential therapeutic alternative(s). CMS is interested in obtaining any additional input that CMS should consider when evaluating the selected drug.

I52: Question 52: For which indication(s) (which includes off-label use(s) per the definition provided in the instructions) would you like to provide input?

Response to Question 52
793/6000 characters

1. Complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥14 kg with no antiretroviral (ARV) treatment history

2. Complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥14 kg with an ARV treatment history and not virologically suppressed, with no known or suspected substitutions associated with the resistance to the integrase inhibitor strand class, emtricitabine, or tenofovir.

3. Complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥14 kg to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies per mL) on a stable ARV regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir.

[RESPONSE HERE]

I53: Question 53: What is your experience with the selected drug or the condition(s) it treats?

Response to Question 53
112/36000 characters

I have personally been prescribed Biktarvy and successfully used the drug to treat HIV/AIDS for nearly a decade.

[RESPONSE HERE]

I54: Question 54: What information or evidence do you think CMS should be aware of as it evaluates the selected drug for each indication(s)? Reference any citations listed in Question 56 when applicable.

Response to Question 54
3551/36000 characters

I was first diagnosed with HIV on April 12th, 2005, in Atlanta, GA, at the AID Atlanta location in Midtown. At the time, treatment protocols in the United States were such that HIV treatments were not prescribed to patients living with HIV until they had received an AIDS diagnosis, which I received on October 19th, 2007, in Ft. Lauderdale, FL.

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The prospect of losing access to HIV medications paid for through Medicare poses a significant risk to PLWHA. Medicare is the 2nd-largest payor of HIV treatment and care in the United States, accounting for 39% of federal spending in 2020, and serving 28% of PLWHA. Additionally, 77% of PLWHA who are enrolled in Medicare first qualified for the program not because of age but because of a disability diagnosis[2].

Biktarvy is, for many people living with HIV/AIDS, a miracle drug. For those of us who remember the "bad old days," being able to take a single medication that doesn't require infusion and has relatively few side effects is a godsend.

The potential that Gilead Sciences could remove its products from Medicare in response to these forced drug price negotiations is one of the greatest threats posed to PLWHA who rely on both Medicare and this medication.

[RESPONSE HERE]

I55_56: Questions 55 and 56: Visual Information and Citations

I55: Question 55: Visual Representations to Support Responses in Section I
Provide up to 20 visual representations such as tables, charts, and/or graphs that support the responses in Section I. Indicate which question each file corresponds to. Regardless of the number of PDF files uploaded in the single Zip file, respondents may not submit more than 20 total visuals (e.g., tables, charts, and/or graphs).

Upload response (up to 20 pdf files in a single zip file):
Choose file to upload or drag and drop file below.
Maximum file size: 50 MB. Allowed file type: .zip.

Choose file to upload or drag and drop file below
Maximum file size: 50 MB Allowed file type: .zip

I56: Question 56: Citations to Support Responses in Section I

Provide up to 250 citations that support the responses provided in Section I. Citations should be labeled with a number corresponding to the number used by the respondent to reference the source in-text throughout Section I. Citations should be listed in the order the citation is first used within Section I. For example, the citation #1 included on the citation list, can be referenced in-text as such (1).

Provide each citation in the National Library of Medicine (NLM) style format appropriate for the source of information (e.g., a journal article). Information on how to format citations is available for free through the NLM at: https://www.ncbi.nlm.nih.gov/books/NBK7256/. When available, please include a Pub Med ID (https://pubmed.ncbi.nlm.nih.gov/) or, if the Pub Med ID is not available, include the Digital Object Identifier (DOI) (https://www.doi.org/). Additionally, please provide a hyperlink to the source, if possible.

Respondents must upload a single PDF document of the list of citations in a Zip file. To create the PDF document, respondents may use an Excel file that includes the information specified in the data fields below for each citation listed by the respondent. For example, each of the bullets below would be a separate column in the table.

- Numbered List
- Full NLM Citation
- PubMed ID, if available
- If the Pub Med ID is not available, the Digital Object Identifier, if available
- Hyperlink, if available

Upload response (up to 250 citations within a pdf file in one zip file):
Choose file to upload or drag and drop file below. Maximum file size: 50 MB. Allowed file type: .zip.
Choose file to upload or drag and drop file below
Maximum file size: 50 MB
Allowed file type: .zip

I57: Question 57: Identification of Information Submitted in Section I that the Respondent Believes Should be Withheld as Proprietary Information

In addition to the information CMS already designates as proprietary consistent with section 40.2.1 of the final guidance: For each question that a respondent to Section I believes contains

information that should be withheld by CMS consistent with existing federal requirements for protecting proprietary information, including under Exemptions 3 and/or 4 of the FOIA, follow the instructions below to identify this information for CMS. This identification of information by a respondent to Section I will be used during CMS' process to determine which information submitted is proprietary and which information may be disclosed in the public explanation of the MFP consistent with section 60.6.1 of the final guidance.

- Using [brackets] at the start and end of any full sentence(s) within a free response field(s) that contains information the respondent believes should be withheld. Also use [brackets] at the start and end of any data provided, if permitted in the data entry field (for example, because the field is a text field), to identify information the respondent believes should be withheld.
  - Label the end of each bracketed sentence with a number in sequential order and use the same number originally assigned to a bracket throughout Section I each time the same justification will be used in response to Question 57 as the reason the respondent believes the information should be withheld (e.g., {1}, {2}). To differentiate references in response to Question 57 from citations, use different symbols for numbering (for example, a {curly brace} for Question 57 and (parenthesis) for citations).
- In the "Location" data field, identify the location of the information the respondent believes should be withheld in Section I by either:
  - For a data response field where brackets cannot be entered (for example, a visual representation) (in other words, a "non-bracketed location"), listing the specific location of the information by identifying the Question number, data entry field, and/or line number to specifically identify the starting and ending point, of information the respondent believes should be withheld.
- In the "Justification" data field, provide a brief explanation regarding why respondent believes the information should be withheld as proprietary information.
  - For a bracketed item, provide the Justification for each separate number used within Section I (e.g., {1}, {2}). Do not repeat the same Justification.
    - If a Primary Manufacturer provides a Section I submission and includes a response to Question 57, restart numbering at {1} in Section I.
  - For a non-bracketed location, if the Justification is the same Justification as a bracketed item, the respondent should use the number assigned to the bracketed item with the corresponding justification as the response to the "Justification" data field. For example, if a non-bracketed item's Justification is the same as the Justification for bracketed item {1}, the respondent should enter "{1}" in the Justification response field for that non-bracketed item."

List of Bracket Locations, in Order of First Appearance (E.g. {1}, {2}); Add a row for each additional item
Not applicable
Row 1
Location
Justification
0/2400 characters
List of Non-Bracketed Locations, Identified by the Section, Question, Data Entry Field and/or Line Number; Add a row for each additional item
Not applicable

Row 1
Location
Justification
0/2400 characters