

**Kriterien zur Bestimmung der zweckmäßigen
Vergleichstherapie**

und

**Recherche und Synopse der Evidenz zur Bestimmung der
zweckmäßigen Vergleichstherapie nach § 35a SGB V**

und

**Schriftliche Beteiligung der wissenschaftlich-medizinischen
Fachgesellschaften und der Arzneimittelkommission der
deutschen Ärzteschaft (AkdÄ) zur Bestimmung der
zweckmäßigen Vergleichstherapie nach § 35a SGB V**

Vorgang: 2026-B-166-z

Darunavir/Cobicistat/Emtricitabin/Tenofoviralfenamid

Stand: September 2026

I. Zweckmäßige Vergleichstherapie: Kriterien gemäß 5. Kapitel § 6 Verfo G-BA

Darunavir/Cobicistat/Emtricitabin/Tenofoviralfenamid [HIV-1-Infektion bei Kindern ≥ 6 bis < 12 Jahre]

Kriterien gemäß 5. Kapitel § 6 Verfo

Sofern als Vergleichstherapie eine Arzneimittelanwendung in Betracht kommt, muss das Arzneimittel grundsätzlich eine Zulassung für das Anwendungsgebiet haben.

Siehe Übersicht „II. Zugelassene Arzneimittel im Anwendungsgebiet“

Sofern als Vergleichstherapie eine nicht-medikamentöse Behandlung in Betracht kommt, muss diese im Rahmen der GKV erbringbar sein.

nicht angezeigt

Beschlüsse/Bewertungen/Empfehlungen des Gemeinsamen Bundesausschusses zu im Anwendungsgebiet zugelassenen Arzneimitteln/nicht-medikamentösen Behandlungen

Beschlüsse zur Nutzenbewertung nach § 35a SGB V:

- Cabotegravir vom 21. Oktober 2021 und vom 7. August 2025
- Fostemsavir vom 16. September 2021
- Ibalizumab vom 18. Februar 2021
- Dolutegravir/Lamivudin vom 6. Februar 2020
- Doravirin/Lamivudin/Tenofoviridisoproxil vom 4. Juli 2019 und vom 20. Oktober 2022
- Doravirin vom 4. Juli 2019 und vom 20. Oktober 2022
- Bictegravir/Emtricitabin/Tenofoviralfenamid vom 20. Dezember 2018 und vom 15. Juni 2023
- Dolutegravir/Rilpivirin vom 6. Dezember 2018
- Darunavir/Cobicistat/Emtricitabin/Tenofoviralfenamid vom 16. März 2018
- Emtricitabin/Rilpivirin/Tenofoviralfenamid vom 5. Januar 2017
- Emtricitabin/Tenofoviralfenamid vom 3. November 2016
- Elvitegravir/Cobicistat/Emtricitabin/Tenofoviralfenamid vom 16. Juni 2016, vom 5. Juli 2018 und vom 20. April 2023
- Dolutegravir/Abacavir/Lamivudin vom 19. März 2015 und vom 17. August 2023
- Cobicistat vom 18. September 2014 und vom 1. Oktober 2020

I. Zweckmäßige Vergleichstherapie: Kriterien gemäß 5. Kapitel § 6 Verfo G-BA

**Darunavir/Cobicistat/Emtricitabin/Tenofovirafenamid
[HIV-1-Infektion bei Kindern ≥ 6 bis < 12 Jahre]**

Kriterien gemäß 5. Kapitel § 6 Verfo

- Dolutegravir vom 7. August 2014 und vom 21. September 2017
- Elvitegravir/Cobicistat/Emtricitabin/Tenofoviridisoproxil vom 5. Dezember 2013 und vom 3. Mai 2018
- Emtricitabin/Rilpivirin/Tenofoviridisoproxil vom 5. Juli 2012 und vom 19. Juni 2014
- Rilpivirin vom 5. Juli 2012 und vom 21. Oktober 2021

Die Vergleichstherapie soll nach dem allgemein anerkannten Stand der medizinischen Erkenntnisse zur zweckmäßigen Therapie im Anwendungsgebiet gehören.

Siehe systematische Literaturrecherche

II. Zugelassene Arzneimittel im Anwendungsgebiet

Wirkstoff ATC-Code Handelsname	Anwendungsgebiet (Text aus Fachinformation)
Zu bewertendes Arzneimittel:	
Darunavir/ Cobicistat/ Emtricitabin/ Tenofoviralfenamid (DRV/COBI/FTC/TAF) J05AR22 Symtuza	Neues Anwendungsgebiet laut Positive Opinion: Symtuza is indicated for the treatment of human immunodeficiency virus type 1 (HIV 1) infection in adults and paediatric patients aged 6 years and older with body weight at least 25 kg.
Proteasehemmer (PI)	
Ritonavir (RTV) J05AE03 generisch	Ritonavir ist als pharmakokinetischer Booster von gleichzeitig verabreichten Proteaseinhibitoren im Rahmen einer antiretroviralen Kombinationstherapie bei Patienten mit einer Infektion durch das Humane Immundefizienz-Virus Typ 1 (HIV-1) angezeigt (Erwachsene und Kinder im Alter von 2 Jahren und älter). <i>[Stand FI Norvir 11/2025]</i>
Atazanavir (ATV) J05AE08 generisch	REYATAZ Pulver zum Einnehmen in Kombination mit niedrig dosiertem Ritonavir ist in Kombination mit anderen antiretroviralen Arzneimitteln zur Behandlung von HIV-1-infizierten Kindern ab 3 Monate und mit mindestens 5 kg indiziert (siehe Abschnitt 4.2). Basierend auf den vorhandenen virologischen und klinischen Daten von Erwachsenen ist für Patienten mit Stämmen, die gegen mehrere Proteaseinhibitoren (≥ 4 PI-Mutationen) resistent sind, kein Nutzen zu erwarten. Die Entscheidung für REYATAZ sollte bei Erwachsenen und Kindern, die bereits antiretroviral vorbehandelt sind, auf individuellen viralen Resistenztests und der Krankengeschichte des Patienten basieren (siehe Abschnitte 4.4 und 5.1). <i>[Stand FI Reyataz 05/2026]</i>

II. Zugelassene Arzneimittel im Anwendungsgebiet

Darunavir (DRV) J05AE10 generisch	PREZISTA zusammen mit niedrig dosiertem Ritonavir eingenommen ist indiziert in Kombination mit anderen antiretroviralen Arzneimitteln zur Therapie von Infektionen mit dem humanen Immundefizienzvirus (HIV-1) bei erwachsenen und pädiatrischen Patienten ab 3 Jahren und mindestens 15 kg Körpergewicht (siehe Abschnitt 4.2). PREZISTA zusammen mit Cobicistat eingenommen ist indiziert in Kombination mit anderen antiretroviralen Arzneimitteln zur Therapie von Infektionen mit dem humanen Immundefizienzvirus (HIV-1) bei Erwachsenen und bei Jugendlichen (ab 12 Jahren, die mindestens 40 kg wiegen) (siehe Abschnitt 4.2). Bei der Entscheidung, die Behandlung mit PREZISTA zusammen mit Cobicistat oder niedrig dosiertem Ritonavir aufzunehmen, sollten die Behandlungsgeschichte des einzelnen Patienten und die mit den verschiedenen Arzneimitteln zusammenhängenden Mutationsmuster besonders berücksichtigt werden. Die Anwendung von PREZISTA sollte sich nach genotypischen oder phänotypischen Resistenzbestimmungen (soweit möglich) und der Behandlungsanamnese richten (siehe Abschnitte 4.2, 4.4 und 5.1). <i>[Stand FI Prezista Suspension 11/2022]</i>
Nukleosidale und nukleotidale Inhibitoren der Reversen Transkriptase (NRTI)	
Zidovudin (AZT) J05AF01 Retrovir	Retrovir zur oralen Anwendung ist angezeigt in der antiretroviralen Kombinationstherapie zur Behandlung von Erwachsenen und Kindern, die mit dem humanen ImmundefizienzVirus (HIV) infiziert sind. Die Chemoprophylaxe mit Retrovir ist angezeigt bei HIV-positiven Schwangeren (nach der 14. Schwangerschaftswoche) zur Prävention der materno-fetalen HIV-Transmission und zur Primärprophylaxe einer HIV-Infektion bei Neugeborenen. <i>[Stand FI Retrovir Lösung 08/2022]</i>
Lamivudin (3TC) J05AF05 generisch	Epivir ist als Teil einer antiretroviralen Kombinationstherapie zur Behandlung von Infektionen mit dem humanen ImmundefizienzVirus (HIV) bei Erwachsenen und Kindern angezeigt. <i>[Stand FI Epivir Lösung 06/2022]</i>
Abacavir (ABC) J05AF06 Ziagen	Ziagen ist angezeigt in der antiretroviralen Kombinationstherapie zur Behandlung von Infektionen mit dem humanen Immundefizienz-Virus (HIV) bei Erwachsenen, Jugendlichen und Kindern (siehe Abschnitte 4.4 und 5.1). Der Wirksamkeitsnachweis von Ziagen basiert hauptsächlich auf Ergebnissen von Studien mit zweimal täglicher Verabreichung, die bei nicht vorbehandelten erwachsenen Patienten in Form einer Kombinationstherapie durchgeführt wurden (siehe Abschnitt 5.1). Vor Beginn der Behandlung mit Abacavir sollte unabhängig von der ethnischen Zugehörigkeit jeder HIV-infizierte Patient auf das Vorhandensein des HLA-B*5701-Allels hin untersucht werden (siehe Abschnitt 4.4). Patienten, bei denen bekannt ist, dass sie das HLA-B*5701-Allel tragen, sollten Abacavir nicht anwenden. <i>[Stand FI Ziagen Lösung 01/2024]</i>

II. Zugelassene Arzneimittel im Anwendungsgebiet

Tenofovirdisoproxil (TDF) J05AF07 generisch	HIV-1-Infektion: Viread 33 mg/g Granulat wird in Kombination mit anderen antiretroviralen Arzneimitteln zur Behandlung HIV-1-infizierter Kinder und Jugendlicher im Alter von 2 bis < 6 Jahren und über 6 Jahren, für die eine feste Darreichungsform nicht geeignet ist, angewendet. Viread 33 mg/g Granulat erhalten Patienten, bei denen der Einsatz von First-Line-Arzneimitteln aufgrund einer Resistenz gegenüber NRTI oder aufgrund von Unverträglichkeiten ausgeschlossen ist. Die Entscheidung für Viread zur Behandlung von antiretroviral vorbehandelten Patienten mit HIV-1-Infektion sollte auf viralen Resistenztests und/oder der Behandlungshistorie der einzelnen Patienten basieren. <i>[Stand FI Viread Granulat 02/2024]</i>
Emtricitabin (FTC) J05AF09 Emtriva	Emtriva wird in Kombination mit anderen antiretroviralen Arzneimitteln zur Behandlung von Erwachsenen und Kindern im Alter von 4 Monaten und darüber, die mit dem humanen Immundefizienzvirus 1 (HIV-1) infiziert sind, angewendet. Diese Indikation beruht auf Studien an nicht vorbehandelten Patienten und an vorbehandelten Patienten mit stabiler virologischer Kontrolle. Es liegen keine Erfahrungswerte über die Anwendung von Emtriva bei Patienten vor, deren gegenwärtige Therapie versagt oder die ein mehrfaches Therapieversagen aufweisen (siehe Abschnitt 5.1). Bei der Entscheidung über ein neues Behandlungsschema für Patienten, bei denen eine antiretrovirale Therapie versagt hat, müssen die Mutationsmuster der verschiedenen Arzneimittel und vorangegangene Therapien beim einzelnen Patienten sorgfältig berücksichtigt werden. Ein Resistenztest – sofern verfügbar – könnte angebracht sein. <i>[Stand FI Emtriva Lösung 11/2022]</i>
Nicht-nukleosidale Inhibitoren der reversen Transkriptase (NNRTI)	
Nevirapin (NVP) J05AG01 generisch	Viramune wird angewendet in Kombination mit anderen antiretroviralen Arzneimitteln zur Behandlung von HIV-1-infizierten Erwachsenen, Jugendlichen und Kindern jeden Alters (siehe Abschnitt 4.2). Die meisten Erkenntnisse beziehen sich auf Viramune in Kombination mit nukleosidischen Reversetranskriptase-Hemmern. Die Entscheidung, welche Therapie nach einer Behandlung mit Viramune gewählt wird, sollte auf klinischer Erfahrung und Resistenztestung basieren (siehe Abschnitt 5.1). <i>[Stand FI Viramune Suspension 10/2024]</i>
Efavirenz (EFV) J05AG03 generisch	Efavirenz ist zur antiviralen Kombinationsbehandlung von humanem Immundefizienz-Virus Typ 1 (HIV-1)-infizierten Erwachsenen, Jugendlichen und Kindern ab 3 Jahre angezeigt. Efavirenz wurde bei Patienten mit fortgeschrittener HIV-Erkrankung, das heißt bei Patienten mit CD4-Zahlen von < 50 Zellen/mm oder nach Versagen von Schemata, die einen Proteaseinhibitor (PI) enthalten, nicht ausreichend untersucht. Eine Kreuzresistenz von Efavirenz mit PIs wurde nicht dokumentiert. Gegenwärtig liegen keine ausreichenden Daten über die Wirksamkeit der sich anschließenden Anwendung einer auf PI-basierenden Kombinationstherapie nach Versagen der Efavirenz enthaltenden Schemata vor. Eine Zusammenfassung der klinischen und pharmakodynamischen Informationen siehe Abschnitt 5.1. <i>[Stand FI Efavirenz Teva 600 mg 02/2023]</i>
Etravirin (ETV) J05AG04 Intelence	Intelence in Kombination mit einem geboosterten Protease-Inhibitor und anderen antiretroviralen Arzneimitteln wird angewendet für die Behandlung von Infektionen mit dem humanen Immundefizienz-Virus 1 (HIV-1) bei antiretroviral vorbehandelten erwachsenen Patienten und bei antiretroviral vorbehandelten pädiatrischen Patienten ab 2 Jahren (siehe Abschnitte 4.4, 4.5 und 5.1). <i>[Stand FI 10/2022]</i>

II. Zugelassene Arzneimittel im Anwendungsgebiet

Rilpivirin (RPV) J05AG05 Edurant	Edurant in Kombination mit anderen antiretroviralen Arzneimitteln wird angewendet zur Behandlung von Infektionen mit dem humanen Immundefizienz-Virus Typ 1 (HIV-1) bei erwachsenen und pädiatrischen Patienten mit einem Körpergewicht von mindestens 25 kg ohne bekannte Resistenz-assoziierte Mutationen gegenüber Arzneimitteln der Klasse der Nicht-Nukleosidischen Reverse-Transkriptase-Inhibitoren (NNRTI) und einer Viruslast von $\leq 100\,000$ HIV-1-RNA-Kopien/ml (siehe Abschnitte 4.4 und 5.1). Die Anwendung von Edurant soll anhand der Ergebnisse des genotypischen Resistenztests ausgerichtet werden (siehe Abschnitte 4.4 und 5.1). <i>[Stand FI 09/2024]</i>
Integraseinhibitoren	
Dolutegravir (DTG) J05AX12 Tivicay	Tivicay ist angezeigt in Kombination mit anderen antiretroviralen Arzneimitteln zur Behandlung von Infektionen mit dem humanen Immundefizienz-Virus (HIV) bei Erwachsenen, Jugendlichen und Kindern ab einem Alter von 4 Wochen , die mindestens 3 kg wiegen. <i>[Stand FI 10/2025]</i>
Raltegravir (RAL) J05AX08 generisch	Isentress ist angezeigt in Kombination mit anderen antiretroviralen Arzneimitteln zur Behandlung einer Infektion mit dem Humanen Immundefizienzvirus (HIV-1) (siehe Abschnitte 4.2, 4.4, 5.1 und 5.2). <i>[Stand FI Isentress Granulat 10/2022]</i>
Andere therapeutische Mittel	
Enfuvirtid (ENV) J05AX07 Fuzeon ¹ Fehler! Textmarke nicht definiert.	Fuzeon wird in Kombination mit anderen antiretroviralen Arzneimitteln angewendet bei HIV-1-infizierten Patienten, die eine Behandlung erhalten haben und ein Therapieversagen gezeigt haben mit Regimen, welche zumindest je ein Arzneimittel aus jeder der antiretroviralen Substanzklassen Proteasehemmer, nicht-nukleosidische Reverse-Transkriptase-Hemmer und nukleosidische Reverse-Transkriptase-Hemmer enthielten, oder die eine Unverträglichkeit gegenüber vorangegangenen antiretroviralen Behandlungsregimen haben (siehe Abschnitt 5.1). Bei der Entscheidung über ein neues Behandlungsregime für Patienten, die gegenüber einem antiretroviralen Regime ein Therapieversagen zeigten, sollen die Behandlungsgeschichte des individuellen Patienten und die Mutationsmuster in Verbindung mit den verschiedenen Arzneimitteln besonders beachtet werden. Sofern verfügbar, können Resistenzuntersuchungen angemessen sein (siehe Abschnitte 4.4 und 5.1). <i>[Stand SmPC 02/2024]</i>
Maraviroc (MVC) J05AX09 Celsentri	Celsentri ist angezeigt in Kombination mit anderen antiretroviralen Arzneimitteln zur Therapie vorbehandelter Erwachsener, Jugendlicher und Kinder ab einem Alter von 2 Jahren und einem Körpergewicht von mindestens 10 kg, bei denen ausschließlich CCR5-trope HI-Viren Typ-1 (HIV-1) nachgewiesen wurden (siehe Abschnitte 4.2 und 5.1). <i>[Stand FI 11/2025]</i>

II. Zugelassene Arzneimittel im Anwendungsgebiet

Kombinationen von antiviralen Mitteln zur Behandlung von HIV-Infektionen

Lamivudin/ Zidovudin (3TC/AZT) J05AR01 Generisch	Lamivudin/Zidovudin ist angezeigt in der antiretroviralen Kombinationstherapie zur Behandlung von Infektionen mit dem humanen Immundefizienz-Virus (HIV) (siehe Abschnitt 4.2). <i>[Stand FI Lamivudin/Zidovudin Mylan 06/2026]</i>
Abacavir/ Lamivudin (ABC/3TC) J05AR02 generisch	Abacavir/Lamivudin ist angezeigt in der antiretroviralen Kombinationstherapie zur Behandlung von Infektionen mit dem humanen Immundefizienz-Virus (HIV) bei Erwachsenen, Jugendlichen und Kindern mit einem Körpergewicht von mindestens 25 kg (siehe Abschnitte 4.4 und 5.1). Vor Beginn der Behandlung mit Abacavir sollte unabhängig von der ethnischen Zugehörigkeit jeder HIV-infizierte Patient auf das Vorhandensein des HLA-B*5701-Allels hin untersucht werden (siehe Abschnitt 4.4). Patienten, bei denen bekannt ist, dass sie das HLA-B*5701-Allel tragen, sollten Abacavir nicht anwenden. <i>[Stand FI Abacavir/Lamivudin Mylan 04/2026]</i>
Lopinavir/ Ritonavir (LPV/RTV) J05AR10 Kaletra	Kaletra ist in Kombination mit anderen antiretroviralen Arzneimitteln zur Behandlung von mit dem humanen Immundefizienz-Virus (HIV-1) infizierten Erwachsenen, Jugendlichen und Kindern im Alter von 14 Tagen und älter angezeigt. Bei bereits mit Proteasehemmern vorbehandelten HIV-1-infizierten Erwachsenen sollte die Anwendung von Kaletra auf einer individuellen virologischen Resistenzuntersuchung und der Behandlungsvorgeschichte des Patienten beruhen (siehe Abschnitte 4.4 und 5.1). <i>[Stand FI Kaletra Lösung 10/2025]</i>
Dolutgravir/ Abacavir/ Lamivudin (DTG/ABC/3TC) J05AR13 Triumeq	Triumeq ist angezeigt zur Behandlung von Infektionen mit dem humanen Immundefizienz-Virus Typ 1 (HIV-1) bei Erwachsenen, Jugendlichen und Kindern, die mindestens 25 kg wiegen (siehe Abschnitte 4.4 und 5.1). Vor Beginn der Behandlung mit Abacavir-haltigen Arzneimitteln sollte unabhängig von der ethnischen Zugehörigkeit jeder HIV-infizierte Patient auf das Vorhandensein des HLA-B*5701-Allels hin untersucht werden (siehe Abschnitt 4.4). Patienten, bei denen bekannt ist, dass sie das HLA-B*5701-Allel tragen, sollten Abacavir nicht anwenden. <i>[Stand FI Triumeq FTA 10/2025]</i>
Darunavir/ Cobicistat (DRV/COBI) J05AR14 Rezolsta ¹	Rezolsta ist in Kombination mit anderen antiretroviralen Arzneimitteln zur Therapie einer Infektion mit dem humanen Immundefizienzvirus-1 (HIV-1) bei Erwachsenen und pädiatrischen Patienten (ab 6 Jahre und mit einem Körpergewicht von mindestens 25 kg) zugelassen. Die Entscheidung über eine Anwendung von REZOLSTA sollte auf Basis der Daten einer Genotypisierung getroffen werden (siehe Abschnitte 4.2, 4.4 und 5.1). <i>[Stand SmPC 08/2025]</i>

II. Zugelassene Arzneimittel im Anwendungsgebiet

Elvitegravir/ Cobicistat/ Emtricitabin/ Tenofoviralfenamid (EVG/COBI/FTC/TAF) J05AR18 Genvoya	Genvoya wird zur Behandlung einer Infektion mit dem humanen Immundefizienzvirus 1(HIV-1) bei Erwachsenen und pädiatrischen Patienten ab 2 Jahren und mit einem Körpergewicht von mindestens 14 kg angewendet. Bei dem HI-Virus dürfen keine bekanntermaßen mit Resistenzen gegen die Klasse der Integrase-Inhibitoren, Emtricitabin oder Tenofovir verbundenen Mutationen nachweisbar sein. (Siehe Abschnitte 4.2 und 5.1.) <i>[Stand FI 10/2022]</i>
Bictegravir/ Emtricitabin/ Tenofoviralfenamid (BIC/FTC/TAF) J05AR20 Biktarvy	Biktarvy wird zur Behandlung einer Infektion mit dem humanen Immundefizienzvirus 1 (HIV-1) bei Erwachsenen und pädiatrischen Patienten ab einem Alter von 2 Jahren und mit einem Körpergewicht von mindestens 14 kg angewendet. Bei dem HI-Virus dürfen weder aktuell noch in der Vergangenheit Resistenzen gegen die Klasse der Integrase-Inhibitoren, Emtricitabin oder Tenofovir nachgewiesen worden sein (siehe Abschnitt 5.1) (Stand: Juni 2024) <i>[Stand FI 12/2025]</i>

1 Derzeit nicht in Deutschland verfügbar.

Quellen: AMLce-Datenbank, Fachinformationen/SmPC

**Recherche und Synopse der Evidenz zur Bestimmung der
zweckmäßigen Vergleichstherapie**

Vorgang: 2026-B-166z (Beratung nach § 35a SGB V)

Darunavir/Cobicistat/Emtricitabin/Tenofoviralfenamid

Auftrag von: Abt. AM
Bearbeitet von: Abt. FB Med
Datum: 7. August 2026

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Abkürzungsverzeichnis

ART	antiretroviral therapy
ATV	Atazanavir
AWMF	Arbeitsgemeinschaft der wissenschaftlichen medizinischen Fachgesellschaften
CAB	Cabotegravir
DRV	Darunavir
ECRI	Emergency Care Research Institute
G-BA	Gemeinsamer Bundesausschuss
GIN	Guidelines International Network
GoR	Grade of Recommendations
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HIV-1	Humanen Immundefizienz-Virus
HR	Hazard Ratio
IBA	Ibalizumab
INSTI	Integrase strand transfer inhibitor
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
KI	Konfidenzintervall
LAAs	Long-acting antiretrovirals
LEN	Lenacapavir
LoE	Level of Evidence
NICE	National Institute for Health and Care Excellence
OR	Odds Ratio
PLWH	people living with HIV
RPV	Rilpivirin
RR	Relatives Risiko
SIGN	Scottish Intercollegiate Guidelines Network
SOT	Standard oral treatment
TAF	tenofovir alafenamide
TDF	Tenofovir disoproxil fumarate
TDR	Transmitted drug resistance
TRIP	Turn Research into Practice Database
WHO	World Health Organization

1 Indikation

Behandlung von Infektionen mit dem Humanen Immundefizienz-Virus (HIV-1) bei Kindern im Alter von 6 bis < 12 Jahren.

Hinweis zur Synopse: Informationen hinsichtlich nicht zugelassener Therapieoptionen sind über die vollumfängliche Darstellung der Leitlinienempfehlungen dargestellt.

2 Systematische Recherche

Es wurde eine systematische Literaturrecherche nach systematischen Reviews, Meta-Analysen und evidenzbasierten systematischen Leitlinien zur Indikation *Humanes Immundefizienz-Virus (HIV-1)* durchgeführt und nach PRISMA-S dokumentiert [A]. Die Recherchestrategie wurde vor der Ausführung anhand der PRESS-Checkliste begutachtet [B]. Es erfolgte eine Datenbankrecherche ohne Sprachrestriktion in: *The Cochrane Library (Cochrane Database of Systematic Reviews)*, *PubMed*. Die Recherche nach grauer Literatur umfasste eine gezielte, iterative Handsuche auf den Internetseiten von Leitlinienorganisationen. Ergänzend wurde eine freie Internetsuche (<https://www.startpage.com>) unter Verwendung des privaten Modus, nach aktuellen deutsch- und englischsprachigen Leitlinien durchgeführt.

Der Suchzeitraum der systematischen Literaturrecherche wurde auf die letzten fünf Jahre eingeschränkt und die Recherchen am 09.03.2026 abgeschlossen. Am 06.07.2026 erfolgte eine Überprüfung der iterativen Handsuche. Die detaillierte Darstellung der Recherchestrategie inkl. verwendeter Suchfilter sowie eine Auflistung durchsuchter Leitlinienorganisationen ist am Ende der Synopse aufgeführt. Mit Hilfe von EndNote wurden Dubletten identifiziert und entfernt. Die Recherchen ergaben insgesamt 2465 Referenzen.

In einem zweistufigen Screening wurden die Ergebnisse der Literaturrecherche bewertet. Im ersten Screening wurden auf Basis von Titel und Abstract nach Population, Intervention, Komparator und Publikationstyp nicht relevante Publikationen ausgeschlossen. Dabei wurde für systematische Reviews, inkl. Meta-Analysen, ein Publikationszeitraum von 2 Jahren und für Leitlinien von 5 Jahren betrachtet. Zudem wurde eine Sprachrestriktion auf deutsche und englische Referenzen vorgenommen. Alle eingeschlossenen Referenzen wurden im Volltext beschafft. Im zweiten Screening wurden die im ersten Screening eingeschlossenen Publikationen im Volltext gesichtet und auf ihre Relevanz und methodische Qualität geprüft. Dafür wurden dieselben Kriterien wie im ersten Screening sowie Kriterien zur methodischen Qualität der Evidenzquellen verwendet.

Basierend darauf, wurden insgesamt 3 Referenzen eingeschlossen. Es erfolgt eine synoptische Darstellung wesentlicher Inhalte der identifizierten Referenzen.

3 Ergebnisse

3.1 Cochrane Reviews

Es konnten keine relevanten Cochrane Reviews identifiziert werden.

3.2 Systematische Reviews

Es konnten keine relevanten Cochrane Reviews identifiziert werden.

3.3 Leitlinien

World Health Organization, 2025 [2, 3].

WHO updated recommendations on HIV clinical management: recommendations for a public health approach

Zielsetzung/Fragestellung

The objective of this guideline is to provide updated evidence-based recommendations on the following points: optimal use of antiretroviral drugs and treatment strategies in all individuals living with HIV whether adults, adolescents, pregnant women or children; [...]

Methodik

Grundlage der Leitlinie

- Repräsentatives Gremium: Trifft zu.
- Interessenkonflikte und finanzielle Unabhängigkeit dargelegt: Trifft zu.
- Systematische Suche, Auswahl und Bewertung der Evidenz: Unklar (*Hinweis: keine vollständige Angabe zu Suchzeitraum und Datum der systematischen Datenbankrecherche*).
- Formale Konsensusprozesse und externes Begutachtungsverfahren dargelegt: Trifft zu.
- Empfehlungen der Leitlinie sind eindeutig und die Verbindung zu der zugrundeliegenden Evidenz ist explizit dargestellt: Trifft zu.
- Regelmäßige Überprüfung der Aktualität gesichert: Unklar.

Recherche/Suchzeitraum:

- Durchführung verschiedener systematischer Reviews basierend auf 9 PICO-Fragestellungen in Übereinstimmung mit den PRISMA-Kriterien
- Nutzung verschiedener Datenbanken für die einzelnen PICO-Fragestellungen: u. a. MEDLINE, EMBASE, CROI, IAS, ClinicalTrials.gov, Cochrane Library
- Der Suchzeitraum wird nur für einzelne systematische Reviews angegeben (B6: 1989–2024, B7: publications up to January 2025, B8: January 2014 to November 2024)

LoE/GoR

- GRADE Framework
- Empfehlungsstärken:
 - Strong recommendation: confidence that the desirable effects of adhering to the recommendation clearly outweigh the undesirable effects

- Conditional recommendation: the certainty of the evidence may be low or may apply only to specific groups or settings

The recommendations listed in this guideline are categorized as follows:

Existing recommendation (not changed) The recommendation was published in previous WHO guidelines. The source of the guideline is provided with the recommendation. The recommendation has not been reviewed or changed since 2021. The evidence base for the recommendation is included in the original source document, as well as in the relevant web annexes of this guideline.	Not changed
Existing recommendation (reviewed and updated) The recommendation was published in previous WHO guidelines, and evidence to inform the recommendation was reviewed for this edition. The supplementary annexes of this guideline include evidence to support the updated or replaced recommendation. The recommendation may replace/complement previous recommendations or the strength/quality evidence of the recommendation may have changed.	Updated
New recommendation The recommendation was not published in previous WHO guidelines and represents new guidance.	New

Sonstige methodische Hinweise

- Für die einzelnen PICO-Fragestellungen wurden Angaben zu den verwendeten Datenbanken sowie teilweise zu den Screeningprozessen gemacht. Das Datum der systematischen Datenbankrecherche und der Suchzeitraum wurden nicht für alle durchgeführten systematischen Reviews bzw. PICO-Fragestellungen spezifiziert.

Empfehlungen

Category	Recommendation	Strength of recommendation	Quality of evidence
Antiretroviral therapy			
Update	Tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF) + lamivudine (3TC) or emtricitabine (FTC) is the preferred nucleoside reverse transcriptase inhibitor (NRTI) backbone for initial and subsequent ART in adults, adolescents and children > 30 kg. This includes individuals previously treated with or exposed to tenofovir.	Strong	Moderate
Update	Abacavir (ABC) or tenofovir alafenamide (TAF) + lamivudine (3TC) or emtricitabine (FTC) is the suggested nucleoside reverse transcriptase inhibitor (NRTI) backbone for subsequent ART in children < 30 kg. This includes children previously treated with ABC or zidovudine (AZT).	Conditional	Low for ABC + 3TC Very low for TAF + 3TC (or FTC)

3.2.3 Supporting evidence

Recycling tenofovir in nucleoside reverse transcriptase inhibitor (NRTI) backbones for adults and adolescents with HIV

Systematic review identified 13 studies evaluating TDF-recycling strategies in adults and adolescents. Eligible studies included direct evidence comparing TDF recycling to AZT switch (five studies) (13–19), studies comparing partially versus fully active NRTIs (five studies) (20–24) and supportive evidence from noncomparative trials (three studies) (5, 25–27).

The most direct evidence comes from the NADIA trial, which was designed to specifically answer this question (13,16). This trial demonstrated that at 96 weeks, adults and adolescents failing an initial regimen who maintained TDF in the subsequent regimen had better viral suppression (+7% [95% CI: 1.2–12.8%]) and CD4 cell count increase (+59 cells/mm³ [95% CI: 18–100 cells/mm³]) compared to those who switched to AZT. This advantage remained consistent across various subgroups, including those with TDF resistance mutations. Recycling TDF was associated with fewer grade 3 and 4 adverse events and decreased risk of resistance, but with imprecise estimates. Among those who developed DTG resistance, five out of seven were on AZT, suggesting that switching to AZT may increase the risk of DTG resistance among those who do not achieve or maintain viral suppression. Regarding the occurrence of discontinuations and weight changes and body mass index, both recycling and switching were comparable, but estimates were imprecise (31).

Three additional studies – ARTIST, D2EFT and VISEND – provided supporting evidence (25–27,29–30). ARTIST is a single-arm study that showed high levels of viral suppression among patients using TLD following failure of a TDF-containing NNRTI-based regimen (26,29). ARTIST also showed that no patient with recycled TDF developed DTG resistance. D2EFT and VISEND compared TLD to boosted PI with optimized or AZT-switched NRTI backbones but could not disaggregate the effects of TDF recycling from DTG (25,30). Nonetheless, both studies found that TLD was noninferior to boosted PI with optimized NRTI backbone, with VISEND finding statistically superior viral suppression with TLD (30).

Evidence favouring TDF recycling instead of switching to AZT was further supported by several observational studies which demonstrated a higher probability of viral suppression among people maintaining tenofovir in subsequent regimens (14,15,17–19,23,24,32,33).

The certainty of evidence on the effects of virological suppression and changes in CD4 cell counts for adults and adolescents failing first-line treatment who maintained tenofovir in the subsequent regimen was rated as moderate. For other outcomes, the certainty of evidence was rated as low.

Recycling abacavir in nucleoside reverse transcriptase inhibitor (NRTI) backbones in children with HIV

Direct evidence on outcomes associated with ABC recycling versus switching to AZT is not available. Evidence from two studies (CHAPAS-4 and ODYSSEY) found ABC associated with a decreased likelihood of virological failures versus AZT at 96 weeks (OR=0.55; 95% CI: 0.40–0.75) (34–40). However, these trials did not randomize children to ABC or AZT (they were designed to evaluate other randomized comparisons) and rates of switching and recycling were not reported. In both studies, children with high or intermediate resistance to ABC were less likely to experience virological failure than those using AZT (OR=0.24; 95% CI: 0.11–0.54). Additional analyses of four longitudinal cohorts examined risk factors associated with the emergence of DTG-based resistance mutations and found that DTG resistance was significantly lower with ABC compared to AZT (OR=0.18, among patients with genotyping; 95% CI: 0.05–0.62) (41). Altogether, these data suggest that ABC use in children was associated with a lower risk of virological failure and DTG resistance than AZT.

The certainty of evidence on virological suppression effects in children failing first-line treatment who continued on ABC in the subsequent regimen was rated as low, given the lack of evidence directly comparing ABC recycling versus AZT switching. For DTG resistance risk, the certainty of evidence was rated as very low, due to the risk of bias and indirectness.

Use of tenofovir alafenamide in adults, adolescents and children with HIV

The systematic review and meta-analysis included 11 randomized clinical trials conducted in adults and adolescents that compared TAF- and TDF-based regimens for at least 24 weeks (42–52). Subgroup analyses were performed to assess whether there were differential effects based on the use of boosted (i.e. containing low-dose ritonavir) or unboosted (i.e. not containing low-dose ritonavir) regimens.

Overall, there was no difference in viral suppression between unboosted TAF- and TDF-containing regimens (RR=1.00; 95% CI: 0.96–1.04). Boosted TDF-containing regimens showed a slightly higher rate of viral suppression compared to boosted TAF-containing regimens (RR=1.03; 95% CI: 1.01–1.04), although the absolute difference was small (1%; 95% CI: 1–1%). No difference in viral suppression was observed in pregnant women, but the evidence is limited (one study) (45). There was no significant difference in mortality: results were very imprecise since the trials were not designed to assess this outcome.

Regarding safety outcomes, there were no significant differences between TAF and TDF for grade 3 and 4 adverse events, severe adverse events and occurrence of bone fractures. No differences were seen between boosted and unboosted subgroups. Renal adverse events (renal tubule adverse events, discontinuations due to renal events) were rare and showed a small but statistically significant difference favouring boosted TAF over boosted TDF regimens (renal tubule adverse events RR=0.17; 95% CI: 0.04–0.84; discontinuations due to renal dysfunction RR=0.19; 95% CI: 0.06–0.55); no events were documented in unboosted regimens. The decline in renal function (measured by eGFR) was lower with TAF than TDF in all seven trials reporting this outcome, but the absolute difference was small (mean difference range: -2.3 to -7.7 mL/min/1.73m²). Rise in total cholesterol was greater with TAF than TDF in all 10 studies reporting the outcome, but the absolute difference for this outcome was also small (mean difference range: +13 to +35 mg/dL).

Pregnancy adverse events were evaluated in one trial (VESTED study), and fewer adverse pregnancy, maternal and child outcomes (preterm delivery, small for gestational age infant, stillbirth or infant deaths) occurred with TAF- compared to TDF-containing regimens (45). No increase in occurrence of congenital defects or specific pattern of congenital abnormalities has been observed with either drug compared to rates in the general population (53).

The certainty of evidence for boosted or mixed TAF and TDF regimens was rated as moderate for viral suppression and low-to-moderate for safety outcomes. For unboosted TAF and TDF regimens, the certainty of evidence was rated as high for viral suppression and moderate for most safety outcomes. Overall, the certainty of evidence was judged to be moderate.

The systematic review did not identify comparative studies of TDF and TAF in children, as TDF is not recommended for use in younger age groups (54). If treated with TDF-containing regimens, younger prepubertal or early pubertal children (ages when there is rapid skeletal growth) may be at higher risk of decreased bone mineral density with TDF than older children and adolescents with more advanced pubertal development. However, TAF can be used in children due to its lower bone toxicity, and there is in fact growing evidence of its use in children and adolescents. Evidence from studies conducted in children aged over two years and in adolescents has demonstrated good efficacy and tolerability of TAF-containing regimens (55,56). A recent observational study of TAF in children and adolescents in Europe found high viral suppression rates (86% (168/196) at 96 weeks) and good safety and tolerability associated with TAF-based ART (56).

Due to the absence of comparative data for TAF and TDF in children, the certainty of evidence was rated as very low.

Table 3.2 Preferred and alternative initial regimens in adults, adolescents, children and neonates

Populations	Preferred initial regimen	Alternative initial regimen	Special circumstances
Adults and adolescents	TDF (or TAF) + 3TC (or FTC) + DTG	TDF + 3TC + EFV 400mg ^a	TDF (or TAF) + 3TC (or FTC) + EFV 600 mg ^a AZT + 3TC + EFV 600 mg ^a ABC + 3TC + DTG TDF (or TAF ^b) + 3TC (or FTC) + DRV/r (or ATV/r or LPV/r)
Children	ABC + 3TC + DTG	TAF + 3TC (or FTC) + DTG ABC + 3TC + DRV/r ^c (or ATV/r or LPV/r ^e)	ABC (or AZT) + 3TC + EFV ^d (or NVP) AZT + 3TC + DRV/r ^c (or ATV/r or LPV/r ^e)
Neonates	ABC + 3TC + DTG ^g	AZT + 3TC + NVP	AZT (or ABC) + 3TC + LPV/r ^f

3TC = lamivudine, ABC = abacavir, ATV/r = atazanavir/ritonavir, AZT = zidovudine, DRV/r = darunavir/ritonavir, DTG = dolutegravir, EFV = efavirenz, FTC = emtricitabine, LPV/r = lopinavir/ritonavir, NVP = nevirapine, TAF = tenofovir alafenamide, TDF = tenofovir disoproxil fumarate

a. EFV-based ART should not be used in settings where national estimates of pre-treatment resistance to EFV are 10% or higher.

b. In adults and adolescents, TAF daily dosage should be reduced from 25 mg to 10 mg when used with boosted PIs.

c. DRV/r is not approved for children under three years of age.

d. EFV should not be used for children younger than three years of age.

e. ATV/r can replace LPV/r for children over three months old but consider limited formulations for those under six years of age, lack of fixed-dose combination and separate ritonavir booster administration.

f. LPV/r syrup or granules can be used if starting after 2 weeks of age.

g. Dolutegravir (DTG) dose of 5 mg every other day (every 48 hours) in the first 2 weeks of life is safe and maintains appropriate drug levels. At age 2 weeks, DTG dosing is increased to 5 mg once every day.

Table 3.3 Preferred and alternative subsequent ART regimens for adults, adolescents, children and infants

Population	Failing initial regimen	Preferred subsequent regimen	Alternative subsequent
Adults, adolescents and children > 30 kg	TDF (or TAF) + 3TC (or FTC) + DTG	TDF (or TAF ^a) + 3TC (or FTC) + DRV/r	TDF (or TAF ^a) + 3TC (or FTC) + ATV/r (or LPV/r)
	TDF (or TAF) + 3TC (or FTC) + EFV	TDF (or TAF) + 3TC (or FTC) + DTG	TDF (or TAF ^a) + 3TC (or FTC) + DRV/r (or ATV/r or LPV/r) AZT (or ABC) + 3TC + DRV/r (or ATV/r or LPV/r)
	AZT + 3TC + EFV	TDF (or TAF) + 3TC (or FTC) + DTG	TDF (or TAF ^a) + 3TC (or FTC) + DRV/r (or ATV/r or LPV/r) ABC + 3TC + DRV/r (or ATV/r or LPV/r)
	ABC + 3TC + DTG	ABC (or TAF) + 3TC (or FTC) + DRV/r	TAF (or ABC) + 3TC (or FTC) + ATV/r ^b (or LPV/r) AZT + 3TC + ATV/r ^b (or LPV/r)
Children < 30 kg and infants	ABC (or AZT) + 3TC + LPV/r	ABC (or TAF) + 3TC (or FTC) + DTG	ABC (or AZT) + 3TC + DRV/r ^c
	AZT + 3TC + NVP	ABC (or TAF) + 3TC (or FTC) + DTG	ABC (or TAF) + 3TC + DRV/r ^c (or ATV/r ^b or LPV/r)

3TC = lamivudine, ABC = abacavir, ATV/r = atazanavir/ritonavir, AZT = zidovudine, DRV/r = darunavir/ritonavir, DTG = dolutegravir, EFV = efavirenz, FTC = emtricitabine, LPV/r = lopinavir/ritonavir, NVP = nevirapine, TAF = tenofovir alafenamide, TDF = tenofovir disoproxil fumarate

a. In adults and adolescents, TAF daily dosage should be reduced from 25 mg to 10 mg when used with boosted PIs.

b. ATV/r can replace LPV/r for children over three months old but consider limited formulations for those under six years of age, lack of fixed-dose combination and separate ritonavir booster administration.

c. DRV/r is not approved for children under three years of age.

Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV, 2026 [1].

Guidelines for the use of antiretroviral agents in pediatric HIV infection.

Zielsetzung/Fragestellung

diagnosis of HIV infection in infants and children and the use of antiretroviral therapy (ART) in children with HIV, (...).

Methodik

Die Leitlinie erfüllt nicht ausreichend die methodischen Anforderungen. Aufgrund limitierter höherwertiger Evidenz hinsichtlich der HIV-1 Behandlung von Kindern, wird die LL jedoch ergänzend dargestellt.

Grundlage der Leitlinie

- Repräsentatives Gremium;
- Interessenkonflikte und finanzielle Unabhängigkeit dargelegt;
- Systematische Suche, Auswahl und Bewertung der Evidenz nicht vollumfänglich beschrieben;
- Formale Konsensusprozesse und externes Begutachtungsverfahren dargelegt;
- Empfehlungen der Leitlinie sind eindeutig und die Verbindung zu der zugrundeliegenden Evidenz ist explizit dargestellt;
- Regelmäßige Überprüfung der Aktualität gesichert: Updated June 25, 2026.

Recherche/Suchzeitraum:

- A standardized review of recent, relevant literature related to each section of the guidelines is performed by a technical assistance consultant (through funding from HRSA) and provided to individual Panel working groups. The recommendations generally are based on studies published in peer-reviewed journals. The Panel may occasionally use unpublished data to revise the guidelines, particularly when the new information relates to dosing or patient safety. These data come from presentations at major conferences or from the FDA and/or drug manufacturers.
- Dürftige Angaben zum Suchzeitraum und Datenbanken. Teilweise Angaben bei entsprechendem Kapitel.

Strength of Recommendation	Quality of Evidence for Recommendation
A: Strong recommendation for the statement B: Moderate recommendation for the statement C: Optional recommendation for the statement	I: One or more randomized trials in children ^a with clinical outcomes and/or validated laboratory endpoints I*: One or more randomized trials in adults with clinical outcomes and/or validated laboratory endpoints, plus accompanying data in children ^a from one or more well-designed, nonrandomized trials or observational cohort studies with clinical outcomes II: One or more well-designed, nonrandomized trials or observational cohort studies in children ^a with clinical outcomes II*: One or more well-designed, nonrandomized trials or observational cohort studies in adults with clinical outcomes, plus accompanying data in children ^a from one or more smaller nonrandomized trials or cohort studies with clinical outcome data III: Expert opinion

^a These studies include children or children and adolescents but not studies that are limited to postpubertal adolescents.

Empfehlungen

Hinweis FBMed: Aktualisierte Empfehlungen sind gelb markiert.

Updated: September 30, 2025

Reviewed: September 30, 2025

Panel's Recommendations
- Antiretroviral therapy (ART) should be initiated in all infants and children with HIV infection (AI for children aged <3 months, AI* for older children). - Rapid ART initiation (defined as initiating ART immediately or within days of HIV diagnosis), accompanied by a discussion of the importance of adherence and provision of subsequent adherence support, is recommended for all children with HIV (AI*). - However, in ART-naïve children and adolescents with cryptococcal meningitis, tuberculous meningitis, and disseminated <i>Mycobacterium avium</i> complex disease, the Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV recommends initiation of treatment for the opportunistic infection first, before ART initiation (see Guidelines for the Prevention and Treatment of Opportunistic Infections in Children With and Exposed to HIV) (AII). The timing of ART initiation in these cases should be discussed with a pediatric HIV specialist. - If a child with HIV has not initiated ART, health care providers should closely monitor the virologic, immunologic, and clinical status at least every 3 to 4 months (AIII). - ART initiation should be discussed and strongly encouraged at every visit (AIII).
Rating of Recommendations: A = Strong; B = Moderate; C = Optional Rating of Evidence: I = One or more randomized trials in children[†] with clinical outcomes and/or validated endpoints; I* = One or more randomized trials in adults with clinical outcomes and/or validated laboratory endpoints with accompanying data in children[†] from one or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; II = One or more well-designed, nonrandomized trials or observational cohort studies in children[†] with long-term clinical outcomes; II* = One or more well-designed, nonrandomized trials or observational studies in adults with long-term clinical outcomes with accompanying data in children[†] from one or more similar nonrandomized trials or cohort studies with clinical outcome data; III = Expert opinion [†]Studies that include children or children/adolescents, but not studies limited to postpubertal adolescents

Hintergrundinformation:

The Panel recommends rapid initiation of ART (defined as initiating ART immediately or within days of HIV diagnosis) for all children who receive an HIV diagnosis, regardless of clinical, immunologic, or virologic status, given the multiple health benefits and potential for minimal HIV viral reservoir size when treatment of initiation occurs within days of birth for infants who are diagnosed with HIV at birth. The urgency of rapid ART initiation is especially critical for children aged <1 year who carry the highest risk of rapid disease progression and mortality. However, in ART-naïve children and adolescents with cryptococcal meningitis, tuberculous meningitis, or disseminated *Mycobacterium avium* complex disease, the Panel recommends initiation of treatment for the opportunistic infection first, before ART initiation (see Guidelines for the Prevention and Treatment of Opportunistic Infections in Children With and Exposed to HIV). Timing of ART initiation in these cases should be discussed with a pediatric HIV specialist. Finally, readiness for good ART adherence should be considered when preparing to initiate ART, as this is the core requirement for successful virologic control. It is important to assess and discuss issues associated with adherence with caregivers and, when developmentally appropriate, with children (see Adherence to Antiretroviral Therapy in Children and Adolescents With HIV). If it is determined that social or emotional challenges will prevent consistent medication adherence, ART initiation may be briefly delayed to address these barriers. If any child with HIV has not initiated ART, health care providers should closely monitor the virologic, immunologic, and clinical status at least every 3 to 4 months, and ART initiation should be discussed and strongly encouraged at every visit.

What to Start: Antiretroviral treatment regimens recommended for initial therapy in infants and children with HIV:

Updated: June 25, 2026

Reviewed: June 25, 2026

Panel's Recommendations
- The selection of an initial antiretroviral regimen for the treatment of HIV in infants and children should be individualized based on factors that include patient characteristics (e.g., age, weight), regimen characteristics (e.g., efficacy, safety, tolerability), clinical and practical considerations, patient and family preferences, and the results of HIV resistance testing (AIII) (see Table A below and Appendix A. Pediatric Antiretroviral Drug Information). - For infants and children initiating treatment for HIV for the first time, the Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV recommends initiating antiretroviral therapy (ART) with three drugs: a dual–nucleoside/nucleotide reverse transcriptase inhibitor (NRTI) backbone plus an integrase strand transfer inhibitor anchor drug, when possible. In some circumstances, an ART regimen of two NRTIs plus a non-nucleoside reverse transcriptase inhibitor or a boosted protease inhibitor as the anchor drug may be indicated for initial treatment (AI*). See Table 8. Antiretroviral Treatment Regimens Recommended for Initial Therapy in Infants and Children With HIV below.
Rating of Recommendations: A = Strong; B = Moderate; C = Optional Rating of Evidence: I = One or more randomized trials in children[†] with clinical outcomes and/or validated endpoints; I* = One or more randomized trials in adults with clinical outcomes and/or validated laboratory endpoints with accompanying data in children[†] from one or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; II = One or more well-designed, nonrandomized trials or observational cohort studies in children[†] with long-term outcomes; II* = One or more well-designed, nonrandomized trials or observational studies in adults with long-term clinical outcomes with accompanying data in children[†] from one or more similar nonrandomized trials or cohort studies with clinical outcome data; III = Expert opinion [†] Studies that include children or children/adolescents, but not studies limited to postpubertal adolescents

Panel Recommendations for Initial Antiretroviral Therapy Regimens in Infants and Children:

Preferred regimen for initial ART in full term infants aged <30 days with HIV-1 infection include an NRTI backbone of two NRTIs plus an INSTI (dolutegravir [DTG]) as the anchor drug **for term newborns ≥37 weeks of gestation**. INSTI-based regimens (INSTI plus two NRTIs) are *Preferred* for initial ART in infants and children aged ≥30 days with HIV-1 infection whenever possible. **Preferred anchor drugs**, by age and weight, are listed below with *Alternative* options discussed in subsections by age group:

- **Full-term** newborns and infants aged <30 days (**gestational age ≥37 weeks**): **DTG** if weight ≥2 kg; see [Table 8](#) below regarding gestational age considerations.
- Infants and children aged ≥30 days: **DTG**
- Children aged ≥2 years and weighing ≥14 kg: **DTG** or bictegravir (**BIC**). **BIC** is available only as a component of the fixed-dose combination (FDC) tablet **BIC/emtricitabine (FTC)/tenofovir alafenamide (TAF)**.

INSTI-based regimens have become the *Preferred* option for initial ART regimens in infants and children (and adults) whenever possible due to their virologic efficacy, lack of drug interactions, and favorable toxicity profile.²⁻⁵ This pediatric recommendation is consistent with recommendations for initial ART in adults and adolescents (see the [What to Start: Initial Combination Antiretroviral Regimens for People With HIV](#) section of the [Adult and Adolescent Antiretroviral Guidelines](#)). Adult comparative trials have shown that INSTI-containing regimens have superior efficacy compared with

PI-containing and NNRTI-containing regimens,^{6,7} and an increasing number of studies have evaluated the PK, safety, tolerability, and efficacy of these drugs in infants, children, and adolescents (see the [Raltegravir](#), [Dolutegravir](#), and [Bictegravir](#) sections).

Raltegravir (RAL) is a first-generation INSTI and is the only INSTI option currently approved by the FDA for use in infants aged <30 days. INSTI-based regimens using second-generation INSTIs that have greater efficacy and a higher barrier to resistance than **RAL** (i.e., **DTG** or **BIC** depending on age and weight) are recommended for initial therapy in children. **Recent data support the use of DTG beginning at birth in full term neonates ≥2 kg.**⁸⁻¹⁰

Selection of Dual-Nucleoside Reverse Transcriptase Inhibitor Backbone as Part of Initial Antiretroviral Therapy Regimens:

Dual-NRTI combinations form the backbone of ART regimens for HIV treatment in both adults and children and are used in combination with an anchor drug from one of the following ARV classes: INSTIs, PIs, or NNRTIs. Dual-NRTI backbones recommended by the Panel as part of *Preferred* or *Alternative* ART regimens for children or for use in special circumstances are listed below, with links to sections in [Appendix A. Pediatric Antiretroviral Drug Information](#) that provide detailed information about the formulations, dosing, safety, and use of each drug in infants and children.

- ([Zidovudine](#) [ZDV] or [abacavir](#) [ABC]) plus ([lamivudine](#) [3TC] or [FTC](#))
- [TAF](#) plus FTC for children weighing ≥14 kg. Some FDCs for complete ART regimens that include TAF have varying weight and age requirements.
- [Tenofovir disoproxil fumarate](#) (TDF) plus 3TC or FTC for children aged ≥2 years and weighing ≥10 kg

Dual-NRTI selection is influenced by a child's weight and age, as well as the availability of FDCs for NRTI combinations or FDCs for complete ART regimens. The advantages and disadvantages of the different dual-NRTI backbone options that are recommended for initial therapy in children are shown in Table 9 and discussed briefly below.

ZDV has been shown to be safe and effective as part of an ART regimen for infants and children. However, hematologic toxicity (anemia, neutropenia)¹¹⁻¹⁵ and twice-daily dosing of ZDV—a requirement for all ages—limit the long-term use of ZDV in children.

ABC is approved by the FDA only for use in children aged ≥ 3 months, but the Panel recommends use of ABC from birth in full-term infants (see [Abacavir](#)).¹⁶⁻¹⁸ A negative test for the human leukocyte antigen (HLA)-B*5701 allele must be obtained prior to use of ABC. HLA screening reduces the risk of ABC-associated hypersensitivity reaction: In a double-blind randomized study, 3.4% incidence of hypersensitivity reaction was diagnosed in the prospective HLA screening group versus 7.8% in the control group.¹⁹ The prevalence of the HLA-B*5701 allele varies globally. In a predominantly white population (~83%) the prevalence is 5.6%, while the prevalence of this genotype in West Africa (including Burkina Faso) and Central Africa (including Uganda) is reported to be very low, at 0.1% in one study²⁰ and 0.2% in another.²¹

3TC and FTC are considered interchangeable as part of ART regimens; both are well tolerated and are associated with few adverse effects (AEs). FTC can be substituted for 3TC as one component of a Preferred dual-NRTI backbone (i.e., FTC plus ABC, TDF, or ZDV). Both 3TC and FTC select for the M184V resistance mutation, which is associated with high-level resistance to both drugs, a modest decrease in susceptibility to ABC, and improved susceptibility to ZDV and TDF (see [Stanford HIV Drug Resistance Database](#)).

TDF is approved for use in children at least 2 years of age. It is available as a stand-alone drug in both powder or tablet formulations and is also contained in multiple FDC products. TDF administration is associated with decreased bone mineral density (BMD) and disruption of vitamin D metabolism in both adults and children.^{22,23} Vitamin D supplementation is recommended for people receiving a TDF-containing regimen who are identified as having vitamin D deficiency (see [Antiretroviral Therapy–Associated Adverse Effects and Management Recommendations—Osteopenia and Osteoporosis](#)). New onset renal impairment and worsening renal impairment have been reported in both adults and children receiving TDF. Although TDF is associated with a decline in glomerular filtration rate, the effect is generally small, and severe glomerular toxicity is rare.^{24,25} Irreversible renal failure is very rare, but cases have been reported.²⁶ With long-term use of TDF, renal toxicity can occur at the site of the proximal convoluted tubules, with clinical manifestations ranging from asymptomatic proteinuria to progressively declining glomerular filtration rates.^{24,27,28} The combination of TDF with atazanavir/ritonavir (ATV/r), darunavir/ritonavir (DRV/r), or lopinavir/ritonavir (LPV/r) increases plasma tenofovir (TFV) concentrations and the risk of TDF-associated toxicity.²⁹

TAF is available only in FDC tablets that must be swallowed whole. With TAF, the active drug TFV achieves higher intracellular concentrations and lower plasma concentrations than TDF. Bone and renal toxicity associated with TDF is linked to higher plasma concentrations of TFV, which may explain why these toxicities occur less frequently with TAF. Use of COBI- or RTV-boosted PIs in combination with TAF/FTC is not recommended in children weighing < 35 kg because these drugs can increase TAF exposure, and no data are available on the use of these combinations. In children and adolescents weighing ≥ 35 kg, boosted PIs can be used with TAF/FTC.

Weight gain and increased risk for clinical obesity have been reported in adults with the use of TAF- and INSTI-containing regimens,^{30,31} but these side effects have not been clearly demonstrated in children.³²⁻³⁴ Furthermore, use of TAF-containing regimens has also been associated with increased levels of total and low-density lipoprotein cholesterol and triglycerides. When these concerns arise, regimens containing TDF may be preferable. However, providers must consider the risks of proximal renal tubular injury, rare irreversible renal failure, and decreased BMD that can occur when TDF is used. Since TAF is associated with less bone and renal toxicity than TDF but has equal antiviral efficacy, TAF is preferred over TDF for most pediatric patients.

Recommended Initial Antiretroviral Therapy Regimens for Infants From Birth to < 30 Days of Age:

Panel recommendations for the anchor drugs for Preferred and Alternative initial ART regimens in infants aged < 30 days (i.e., DTG, RAL, nevirapine [NVP], and LPV/r) is dependent on gestational age at birth, the infant's postmenstrual age (calculated as gestational age at birth plus postnatal age), and current weight at the time the ARV regimen or specific ARV drug is initiated.³⁵

Preferred Regimens

- Term infants (≥ 37 weeks gestation) or preterm infants with a postmenstrual age ≥ 37 weeks at the time of treatment initiation:
 - DTG (for infants weighing ≥ 2 kg) plus ZDV plus (3TC or FTC) or
 - NVP (for infants weighing < 2 kg) plus ZDV plus (3TC or FTC)
- Preterm infants with a postmenstrual age ≥ 32 weeks to < 37 weeks at the time of treatment initiation:
 - NVP plus ZDV plus (3TC or FTC)
- Preterm infants with a postmenstrual age < 32 weeks at the time of treatment initiation:
 - Consultation with a pediatric HIV expert or the [National Perinatal HIV/AIDS Hotline](#) (1-888-448-8765) is recommended.

Rationale

The Panel recommends DTG administered with an NRTI backbone of ZDV plus 3TC or FTC as an initial regimen for the treatment of HIV-1 infection in infants born at ≥ 37 weeks and weighing ≥ 2 kg.³⁶⁻⁴² NVP administered with an NRTI backbone of ZDV plus 3TC or FTC is Preferred as an initial regimen for preterm infants or term infants weighing < 2 kg. The selection of anchor drug and regimen will depend on several factors, such as ARV resistance during pregnancy, the infant's gestational age at birth, current postmenstrual age, weight at treatment initiation, the caregiver's perceived ease of preparing and dosing, availability of appropriate formulations, and availability of medications in the outpatient setting. These factors have been summarized below in Table B. Advantages and Disadvantages of ARVs Recommended for Initial Antiretroviral Therapy in Infants From Birth to < 30 Days of Age. HIV resistance testing and HLA-B*5701 should be included in the initial workup for all infants and children with HIV at the time of HIV diagnosis and before initiation of ART but should not delay treatment initiation. Initial ART regimens can be modified if needed based on drug resistance testing results (see [Clinical and Laboratory Monitoring of Pediatric HIV Infection](#)).

ABC: A negative test for the HLA-B*5701 allele must be obtained prior to use of ABC. Although ABC is not FDA approved for use in infants aged <3 months, the Panel recommends ABC as part of an *Alternative* NRTI backbone for full-term infants from birth (see [Abacavir](#)). An ABC dosing recommendation using PK simulation models has been endorsed by the World Health Organization (WHO) using weight-band dosing for full-term neonates. A recent study of infants with HIV in a South African cohort, stratified by age (<28 days and ≥28 days) and weight (<3 kg and ≥3 kg), demonstrated the safety and effectiveness of ABC in infants aged <3 months and in neonates weighing <3 kg.^{8,16,17,46}

Table B. Advantages and Disadvantages of Anchor Drugs Recommended for Initial Antiretroviral Therapy Regimens in Infants From Birth to <30 Days of Age

Anchor Drugs*	Advantages	Disadvantages
DTG (Preferred)	• Preferred INSTI • Can be started at birth and continued through adulthood • Available as a single dose every other day for the first 2 weeks, followed by a daily dose thereafter • Available as a well-tolerated dispersible tablet suitable for use in neonates.	• Not yet FDA approved. ViiV/GSK to submit to FDA in January 2026. • Limited to use in term infants (≥37 weeks of gestation and weight ≥2 kg) or preterm infants with a postmenstrual age ≥37 weeks at the time of treatment initiation. • Every other day dosing during the first 2 weeks of life may be challenging for some caregivers. Additional education and/or dosing calendars, telephone reminders, or other adherence tools may be required.
RAL (Alternative)	• FDA-approved INSTI for use in term newborns weighing ≥2 kg • Produces rapid reduction in viral load • Safe and well tolerated • Avoids use of NVP and exposure to another class of ARVs (NNRTIs)	• First-generation INSTI with lower barrier to resistance than DTG or BIC • Granule formulation requires a multistep preparation before administration. • Caregivers must be taught how to properly prepare granule formulation. Explain that only a small volume of the prepared granule suspension is used; the rest must be discarded and cannot be reused. • Limited to use in term infants (≥37 weeks of gestation) or preterm infants with a postmenstrual age ≥37 weeks at the time of treatment initiation
NVP (Alternative for full-term infants and Preferred for preterm infants and term infants weighing <2 kg)	• Available in convenient oral solution • Can be used in preterm newborns with a gestational age ≥32 weeks • Extensive experience with NVP, including breastfeeding prophylaxis	• Not a Preferred ARV due to the potential for toxicity and development of viral resistance, although it can be used if clinically indicated • Reduced virologic efficacy in young infants, regardless of exposure to NVP as part of a peripartum preventive regimen • A single mutation can confer resistance to this drug and, in some instances, to all NNRTIs.

At the time of HIV diagnosis, some infants at high risk for HIV acquisition may have initiated presumptive HIV therapy. The regimens recommended for presumptive HIV therapy are addressed in *Antiretroviral Management of Infants With In Utero, Intrapartum, or Breastfeeding Exposure to HIV* and are the same as the ARV regimens recommended for treatment of HIV in neonates. Therefore, once the diagnosis of HIV-1 is established in the neonate, the regimen for presumptive HIV therapy can be continued—now as definitive ART—with virologic monitoring to establish successful viral suppression (see [Clinical and Laboratory Monitoring of Pediatric HIV Infection](#)).

At the time of HIV diagnosis, some infants at low risk for HIV acquisition might be receiving ZDV alone as prophylaxis. If the infant has a positive HIV nucleic acid test, a complete ART regimen should be initiated without waiting for the results of a confirmatory test. In this case, ZDV may be continued with the addition of a second NRTI and DTG as long as the infant's postmenstrual age is ≥37 weeks and weight is ≥2 kg. *Alternative regimens including RAL, NVP, or an LPV/r-based regimen appropriate for the infant's age and weight can be used (see Alternative Regimens below).* If confirmatory testing indicates the infant does not have HIV, ART can be discontinued.

Alternative Regimens

Alternative Anchor Drug

RAL (for infants weighing ≥2 kg) plus ZDV plus (3TC or FTC):

The Panel recommends RAL in combination with the NRTI backbone recommended in *Preferred* Regimens above as an *Alternative* anchor drug for infants. Although RAL is the only INSTI currently approved by the FDA for use in neonates, it has a lower barrier to viral resistance than DTG, involves a multistep process for preparation, and has a complicated dosing schedule for the first few weeks of life.⁴³⁻⁴⁵ There is extensive experience with RAL in full-term neonates.

NVP plus ZDV plus (3TC or FTC):

The Panel continues to recommend NVP in combination with the NRTI backbone recommended in *Preferred* Regimens above as a *Preferred* drug for preterm infants and as an *Alternative* for full-term infants ≥2 kg; for infants weighing <2 kg, NVP continues to be a *Preferred* anchor drug. There is extensive data on the efficacy and safety of NVP in children. Infants with a postmenstrual age ≥42 weeks and a postnatal age of ≥14 days:

LPV/r plus ZDV plus (3TC or FTC):

The Panel recommends LPV/r oral solution in combination with the NRTI backbone recommended in *Preferred* Regimens above as an *Alternative* anchor drug for infants with a postmenstrual age of ≥42 weeks of gestation and a postnatal age of ≥14 days. LPV/r oral solution contains 42.4% (volume/volume) alcohol and 15.3% (weight/volume) propylene glycol. Use of this drug in infants before 42 weeks postmenstrual age and before a postnatal age of 14 days, when hepatic metabolic function and kidney excretory function are maturing, can lead to accumulation of LPV, alcohol, and propylene glycol, resulting in serious cardiac, renal, metabolic, or respiratory problems. For more information about LPV/r use in newborns, refer to the [Lopinavir/Ritonavir](#) section in [Appendix A, Pediatric Antiretroviral Drug Information](#).

Alternative Nucleoside Reverse Transcriptase Inhibitor Backbone

- Term infants (≥37 weeks gestation):
 - [ABC](#) plus (3TC or FTC) if HLA-B*5701 negative

Table B. Advantages and Disadvantages of Anchor Drugs Recommended for Initial Antiretroviral Therapy Regimens in Infants From Birth to <30 Days of Age

Anchor Drugs ^a	Advantages	Disadvantages
LPV/r (Alternative)	- Available in convenient oral solution - More durable than RAL or NVP	- Should not be administered to neonates before a postmenstrual age of 42 weeks (calculated as gestational age at birth plus postnatal age) and a postnatal age <14 days - Poor palatability and bitter taste may cause incomplete dosing if infant spits it out. More side effects than other ARVs used in this age group.

^a This table focuses on advantages and disadvantages regarding the selection of anchor drugs for ART regimens used in infants aged <30 days. Additional information is available in Table 9. Advantages and Disadvantages of Antiretroviral Components Recommended for Initial Therapy in Infants and Children.

Key: ART = antiretroviral therapy; ARV = antiretroviral; BIC = bictegravir; DTG = dolutegravir; FDA = U.S. Food and Drug Administration; INSTI = integrase strand transfer inhibitor; LPV/r = lopinavir/ritonavir; NNRTI = non-nucleoside reverse transcriptase inhibitor; NVP = nevirapine; RAL = raltegravir

Recommended Initial Antiretroviral Therapy Regimens for Infants and Children Aged ≥30 Days to <2 Years

Preferred Regimens

- Aged ≥30 days to <2 years: **ART should be initiated with a DTG-based regimen.** Transition to a DTG-based regimen should be considered **if an infant is initiated on an NVP-, RAL-, or LPV/r-based regimen in the first month of life.**
 - DTG plus ABC plus (3TC or FTC) if HLA-B*5701 negative **or**
 - DTG plus ZDV plus (3TC or FTC) **or**
- Aged ≥3 months to <2 years and weighing ≥6 kg to <25 kg
 - DTG plus ABC plus 3TC as an FDC (Triumeq PD) if HLA-B*5701 negative

For preterm infants who have not yet achieved a postmenstrual age of 37 weeks at 30 days of age, therapy should be initiated using the recommended initial ART regimen for preterm infants, with NVP

as the anchor drug (see Initial ART Regimens for Infants From Birth to <30 Days of Age above) and transitioning to a DTG-based regimen when postmenstrual age is ≥37 weeks and weight is ≥2 kg.

The Panel supports the use of the single ABC/3TC/DTG FDC dispersible tablet as an alternative to the separate formulations of ABC, 3TC, and DTG in infants weighing ≥3 kg to <6 kg and aged ≥4 weeks to facilitate treatment adherence. Although this FDC is not FDA-approved in this population, the Panel's recommendation is based on population PK modeling of data from IMPAACT 2019, IMPAACT P1093, ODYSSEY clinical trials for DTG, and the PETITE clinical trial for ABC and 3TC.^{2,17,18,49-51}

Alternative Regimens

Alternative Anchor Drugs

- LPV/r:** LPV is available as an oral solution coformulated with RTV, and twice-daily dosing is recommended. LPV/r should be administered with food to improve tolerability.^{39,54,55} Poor taste and palatability of the oral solution may become an issue for young children and limit acceptance of this regimen. LPV/r has a high genetic barrier to drug resistance. However, poor acceptance of formulation, gastrointestinal side effects, and poor weight gain may limit its use in this age group.⁵⁶
- ATV/r:** ATV/r can be considered an *Alternative* to LPV/r in children weighing ≥15 kg.⁵⁷ ATV and RTV are available as separate powder packets that are mixed with either soft food or formula and administered once daily. The powder formulation of ATV can be used in children weighing ≥15 kg to <25 kg. The powder formulations have poor palatability and may be difficult to tolerate in this age group.
- NNRTIs:** NVP could be considered if there is resistance or intolerance to both PIs and INSTIs. However, NVP is generally not recommended as an initial treatment in this age group because the low genetic barrier to resistance during a time of significant viremia may lead to drug resistance to all members of the NNRTI class of drugs.⁴⁰ Efavirenz (EFV) is not recommended

for children <3 years of age due to highly variable PK in young children, difficulty in determining an appropriate dose without therapeutic drug monitoring, and side effects (i.e., neurologic toxicity).⁵⁸

Nucleoside Reverse Transcriptase Inhibitor Backbones in *Alternative* Regimens

- Twice-daily dosing: An NRTI backbone of ZDV plus 3TC twice daily or ABC plus 3TC twice daily allows for all medications to be administered at the same time when given in combination with LPV/r or RAL. There is considerable experience with ZDV and 3TC in this age group. ABC is associated with less bone marrow toxicity than ZDV and may be the *Preferred* NRTI for long-term use.

Recommended Initial Antiretroviral Therapy Regimens for Children Aged ≥ 2 Years to < 12 Years:

Preferred Regimens for Children Aged ≥ 2 Years to < 12 Years Who Are Not Able to Swallow Pills

- [DTG](#) plus [ABC](#) plus [3TC](#) in the dispersible FDC formulation (Triumeq PD) for children weighing 6 kg to < 25 kg if HLA-B*5701 negative **or**
 - [DTG](#) film-coated tablets (Tivicay) plus [ABC](#) plus ([3TC](#) or [FTC](#)) in liquid formulations for children weighing ≥ 25 kg if HLA-B*5701 negative (see [Dolutegravir](#) for special instructions about administering DTG tablets to children who are not able to swallow pills)
- [DTG](#) plus [FTC](#) plus [TAF](#) for children weighing ≥ 14 kg (see [Dolutegravir](#) and [Tenofovir Alafenamide](#) for available formulations of DTG [Tivicay, Tivicay PD], dosage strengths of [FTC/TAF](#) [Descovy], and special instructions for administering DTG film-coated tablets and [FTC/TAF](#) tablets to children who are not able to swallow pills) **or**
- [DTG](#) in dispersible tablets plus [ZDV](#) plus ([3TC](#) or [FTC](#)) in liquid formulations

The dispersible FDC tablet of DTG/ABC/3TC (Triumeq PD) is a once-daily regimen shown to be efficacious in the Phase 1/2 IMPAACT 2019 study among children aged < 12 years and weighing 6 kg to 40 kg.⁵³ A child must have a negative HLA-B*5701 allele screening test before initiating treatment to ensure that the child will not be at risk for a hypersensitivity reaction to ABC.

When the DTG/ABC/3TC dispersible FDC tablet cannot be used (i.e., it is not available or results of HLA-B*5701 testing are unknown or positive) and the child weighs < 14 kg at treatment initiation, the Panel recommends initiating a regimen of DTG plus ZDV plus 3TC. DTG is available as dispersible tablets (Tivicay PD) dosed once daily, which can be used in children weighing 6 kg to < 25 kg. ZDV and 3TC are both available in liquid formulations and require twice-daily dosing. If DTG/ABC/3TC cannot be used and the child weighs ≥ 14 kg, DTG plus FTC/TAF (Descovy) is recommended by the Panel. FTC/TAF (Descovy) is available in two different-strength tablets, with the lower-strength tablet for children weighing ≥ 14 kg to < 25 kg.

Preferred Regimens for Children Aged ≥ 2 Years to < 12 Years Who Are Able to Swallow Pills

For children weighing < 14 kg, see regimens listed above for children who are not able to swallow pills.

- [BIC](#) plus [FTC](#) plus [TAF](#) (FDC [BIC/FTC/TAF](#), Biktarvy) for children weighing ≥ 14 kg
- [DTG](#) plus [FTC](#) plus [TAF](#) ([DTG](#), Tivicay, plus the FDC [FTC/TAF](#), Descovy) for children weighing ≥ 14 kg
- [DTG](#) plus [ABC](#) plus [3TC](#) (FDC [DTG/ABC/3TC](#), Triumeq) for children weighing ≥ 25 kg if HLA-B*5701 negative

Alternative Regimens

Anchor Drugs

When concern for INSTI resistance exists, the following anchor drugs represent *Alternative* treatment options when paired with two fully active NRTIs.

- **ATV plus RTV or COBI:** ATV is available as a powder packet that should be mixed with solid food and administered once daily. ATV powder can be coadministered with RTV once daily for a child ≥ 3 months and weighing ≥ 5 kg to ≤ 25 kg. However, because RTV oral solution is no longer commercially available, use of ATV/r is limited to children weighing ≥ 15 kg who can use the RTV 100-mg powder packet or 100-mg tablet. The RTV powder formulation has poor palatability and may be difficult to tolerate. For a child weighing ≥ 15 kg who can swallow pills, the capsule formulation of ATV can be dosed once daily with the RTV tablets (i.e., ATV/r) in children who are ≥ 6 years of age. Boosting ATV with COBI is an option only if the child weighs ≥ 35 kg and can swallow pills and is available as a FDC of COBI-boosted ATV (ATV/c) that can be administered once daily.
- **DRV plus RTV or COBI:** DRV is an option for children aged ≥ 3 years to < 12 years and weighing ≥ 20 kg. However, DRV requires a PK enhancer or boosting agent, such as RTV or COBI. DRV is available as a solution or tablet that can be administered twice daily with an RTV powder packet or tablet. Boosting DRV with COBI is an option only if the child weighs ≥ 25 kg. COBI-boosted DRV (DRV/c) is available in a once-daily FDC (Prezcobix), with two strengths available, DRV/c

675 mg/150 mg for children weighing ≥ 25 kg to < 40 kg and DRV/c 800 mg/150 mg for those weighing ≥ 40 kg.

- **NNRTIs:** An NNRTI-based regimen using NVP, EFV, or doravirine (DOR) could be considered in the case of resistance or intolerance to both PIs and INSTIs. EFV is not recommended by the Panel for use in children aged < 3 years due to highly variable PK in young children, difficulty in determining an appropriate dose without therapeutic drug monitoring, and side effects (i.e., neurologic toxicity) (see [Efavirenz](#)). DOR is approved for use in children weighing ≥ 35 kg, and recent data found that once-daily dosing of DOR/3TC/TDF was safe and well tolerated for maintaining viral suppression through 96 weeks in adolescents.⁶⁸

Table 8. Antiretroviral Treatment Regimens Recommended for Initial Therapy for HIV Infection in Infants and Children: Birth to <12 Years of Age

Preferred Initial Regimens and ARV Drugs Based on Age and Weight at Time of Treatment Initiation			
8A. Infants From Birth to <30 Days of Age			
Panel Recommendation ^{a,b}	Regimen or ARV Drug	Age and/or Weight Restriction ^c	Formulations and Comments ^c
Preferred ART regimens for infants ≥ 37 weeks of gestation and aged <30 days and preterm infants with a postmenstrual age of ≥ 37 weeks at treatment initiation	INSTI (DTG) plus two NRTIs - DTG plus ZDV plus (3TC or FTC) - NVP plus ZDV plus (3TC or FTC)	≥ 2 kg (DTG) < 2 kg at birth (NVP)	Dispersible tablet for oral suspension (DTG) plus oral solutions for NVP, ZDV plus (3TC or FTC)
Preferred ART regimen for preterm infants ≥ 32 to <37 weeks of gestation	NNRTI (NVP) plus two NRTIs NVP plus ZDV plus (3TC or FTC)	None	All oral solutions
Preferred ART regimens for preterm infants <32 weeks of gestation	Consultation with a pediatric HIV expert or the National Perinatal HIV/AIDS Hotline (1-888-448-8765) is recommended		
Alternative ART regimens for infants	PI (LPV/r) plus two NRTIs LPV/r plus ZDV plus (3TC or FTC)	Postmenstrual age ≥ 42 weeks and a postnatal age of > 14 days (LPV/r)	All oral solutions
	NNRTI (NVP) plus two NRTIs NVP plus ZDV plus (3TC or FTC)	≥ 32 weeks of gestation	All oral solutions
	INSTI (RAL) plus two NRTIs RAL plus ZDV plus (3TC or FTC)	≥ 2 kg (RAL)	RAL granules for oral suspension plus oral solutions for ZDV plus (3TC or FTC)
Alternative NRTI backbone for infants	ABC plus (3TC or FTC) if HLA-B*57:01 negative	≥ 37 weeks of gestation	All oral solutions Use of ABC ^d requires negative HLA-B*57:01 results.

Preferred Initial Regimens and ARV Drugs Based on Age and Weight at Time of Treatment Initiation			
8B. Infants and Children Aged ≥30 Days to <2 Years			
Panel Recommendation ^{a,b}	Regimen or ARV Drug	Age and/or Weight Restriction ^c	Formulations and Comments ^c
Preferred ART regimens for infants and children aged ≥30 days to <2 years	INSTI (DTG) ^{a,f} plus two NRTIs	DTG ≥30 days and ≥3 kg to <25 kg	DTG dispersible tablets plus oral solutions (ABC ^g , ZDV, 3TC, or FTC)
	• DTG plus ZDV plus (3TC or FTC) or		
	• DTG plus ABC plus (3TC or FTC) if HLA-B*5701 negative	DTG ≥30 days and ≥3 kg to <25 kg	
	• DTG/ABC/3TC in FDC if HLA-B*5701 negative	≥3 months and ≥6 kg to <25 kg (Triumeq PD)	DTG/ABC/3TC in FDC dispersible tablets (Triumeq PD)
Alternative anchor drugs to replace DTG in an ART regimen with a Preferred NRTI backbone for infants and children aged ≥30 days to <2 years		≥25 kg (Triumeq)	DTG/ABC/3TC FDC tablets if ≥25 kg (Triumeq). See Dolutegravir for special instructions if a child is unable to swallow pills.
	Boosted PI	Postmenstrual age ≥42 weeks and postnatal age >14 days	LPV/r is available in an oral solution.
	• LPV/r ^f (boosted PI)		
	• ATV plus RTV (boosted PI)	ATV ≥15 kg to <25 kg	ATV is available in powder packets; RTV is available in 100-mg tablets and 100-mg powder packets.
	NNRTI	<3 years	NVP is available in an oral solution.
	NVP (NNRTI)		

Preferred Initial Regimens and ARV Drugs Based on Age and Weight at Time of Treatment Initiation			
8C. Children Aged ≥2 Years to <12 Years			
Panel Recommendation ^{a,b}	Regimen or ARV Drug	Age and/or Weight Restriction ^c	Formulations and Comments ^c
Preferred ART regimens for children aged ≥2 years to <12 years who are unable to swallow pills	INSTI (DTG) plus Two NRTIs		For children who are unable to swallow pills
	• DTG/ABC/3TC in FDC if HLA-B*5701 negative	≥3 months and 3 kg to <25 kg (Triumeq PD)	DTG/ABC/3TC is available in FDC dispersible tablets (Triumeq PD).
	• DTG plus ZDV plus (3TC or FTC)	≥30 days and ≥3 kg (DTG)	DTG is available in dispersible tablets and taken with oral solutions (ZDV, 3TC, or FTC).
	• DTG plus FTC/TAF; FTC/TAF in FDC (Descovy)	≥30 days and ≥3 kg (DTG) ≥14 kg to <25 kg (FTC/TAF)	TAF is available as FTC/TAF in FDC (Descovy) only, not as an individual drug. See Tenofovir Alafenamide for special instructions about administering FTC/TAF to children who are not able to swallow pills. For children who are ≥25 kg and unable to swallow pills, see Dolutegravir and Tenofovir Alafenamide for special instructions about administering DTG 50 mg and FTC/TAF (FTC 200 mg/TAF 25 mg).

Preferred Initial Regimens and ARV Drugs Based on Age and Weight at Time of Treatment Initiation			
8C. Children Aged ≥2 Years to <12 Years			
Panel Recommendation ^{a,b}	Regimen or ARV Drug	Age and/or Weight Restriction ^c	Formulations and Comments ^c
Preferred ART regimens for children aged ≥2 years to <12 years who are able to swallow pills	INSTI (BIC or DTG) plus Two NRTIs		For children who are able to swallow pills
	• BIC plus FTC plus TAF in FDC ^{d,h}	Aged ≥2 years and ≥14 kg to <25 kg (BIC 30 mg/FTC 120 mg/TAF 15 mg) ≥25 kg (BIC 50 mg/FTC 200 mg/TAF 25 mg)	BIC is available only in the FDC BIC/FTC/TAF. The product label states that for children who are unable to swallow a whole tablet, the BIC/FTC/TAF tablet can be split and each part taken separately, as long as all parts are ingested within approximately 10 minutes; see Bictegravir .
	• DTG plus ABC plus 3TC in FDC if HLA-B*5701 negative	≥25 kg	DTG/ABC/3TC is available in FDC tablets (Triumeq).
	• DTG plus FTC/TAF ; FTC/TAF in FDC (Descovy) ⁱ	≥14 kg (DTG tablets [Tivicay] and FTC/TAF tablets)	TAF is available only as FTC/TAF in FDC (Descovy); not available as an individual drug. See Tenofovir Alafenamide .

Preferred Initial Regimens and ARV Drugs Based on Age and Weight at Time of Treatment Initiation			
8C. Children Aged ≥2 Years to <12 Years			
Panel Recommendation ^{a,b}	Regimen or ARV Drug	Age and/or Weight Restriction ^c	Formulations and Comments ^c
Alternative anchor drugs in an ART regimen with a Preferred NRTI backbone for children aged ≥2 years to <12 years ⁱ	• ATV powder plus RTV powder (boosted PI)	≥15 kg to ≤25 kg	ATV is available in 50-mg powder packets; RTV is available in 100-mg powder packets.
	• ATV capsules plus RTV tablets (boosted PI)	≥15 kg	ATV and RTV powder can be mixed with soft food or liquid.
	• ATV plus COBI in FDC tablet (ATV/c, boosted PI)	≥35 kg	
	• DRV plus RTV (boosted PI)	≥20 kg	DRV is available in an oral solution or tablets to be taken with RTV powder or tablets.
	• DRV plus COBI in FDC tablet (DRV/c, boosted PI)	≥25 kg	
	• NVP	None	NVP is available in an oral solution or immediate-release tablets.
	• NVP XR	Aged ≥6 years	
	• EFV	Aged ≥3 years and ≥10 kg	EFV capsules can be opened and used as a sprinkle formulation for children who are unable to swallow pills.
	• DOR	≥35 kg	DOR is available as a single-tablet regimen (DOR/3TC/TDF).

^a Panel recommendations summarized in this table are for children with HIV-1 infection.

^b Recommendations for ARV drugs or ART regimens to be used in special circumstances are addressed in the text (e.g., ARV resistance, HBV coinfection).

^c Additional information about FDCs is available in [Appendix A. Pediatric Antiretroviral Drug Information](#), [Appendix A, Table 1. Antiretrovirals Available in Fixed-Dose Combination Tablets or as a Co-packaged Formulation, by Drug Class](#), and [Appendix A, Table 2. Antiretroviral Fixed-Dose Combination Tablets and Co-packaged Formulations: Minimum Body Weights and Considerations for Use in Children and Adolescents](#).

^d ABC is not approved by the FDA for use in full-term neonates and infants aged <3 months. Recent data from the IMPAACT P1106 trial and two observational cohorts provide reassuring data on the safety of ABC in infants when initiated at the age of <3 months (see [Abacavir](#)). Before ABC administration, a negative HLA-B*5701 allele test result should be available. An FDC tablet that contains ABC/3TC (generic) is available for use in children weighing ≥25 kg.

^e If DTG dispersible tablets are not available, RAL can be administered using either the oral granules for suspension dispersed in water or the chewable tablets dispersed in juice, formula, or milk.

[†] An NRTI backbone of ZDV plus 3TC twice daily or ABC plus 3TC twice daily allows for all medications to be administered at the same time when given in combination with LPV/r or RAL. There is considerable experience with ZDV and 3TC in this age group. ABC is associated with less bone marrow toxicity than ZDV and may be the preferred NRTI for long-term use.

[§] BIC/FTC/TAF tablets are available in two different strengths, with the lower-strength tablet for children weighing ≥ 14 kg and < 25 kg.

^h The product label for BIC/FTC/TAF (Biktarvy) states that for children who are unable to swallow a whole tablet, the BIC/FTC/TAF tablet can be split and each part taken separately, as long as all parts are ingested within approximately 10 minutes.

[†] FTC plus TAF is recommended as a *Preferred* NRTI combination for children and adolescents weighing ≥ 14 kg when used with an INSTI or NNRTI; an FDC tablet that contains FTC/TAF (Descovy) is available in two strengths, with dosage determined by a child's weight (see [Tenofovir Alafenamide](#)). FTC/TAF is approved by the FDA for children weighing ≥ 14 kg when used in the regimen BIC/FTC/TAF, which is also available in two strengths, with dosage determined by a child's weight. FTC/TAF is a *Preferred* NRTI combination for children and adolescents weighing ≥ 35 kg when used with a boosted PI; FTC/TAF is not approved or recommended for use with a boosted PI in children weighing < 35 kg.

Key: 3TC = lamivudine; ABC = abacavir; ARV = antiretroviral; ART = antiretroviral therapy; ATV = atazanavir; BIC = bictegravir; COBI = cobicistat; DOR = doravirine; DRV = darunavir; DRV/c = darunavir/cobicistat; DTG = dolutegravir; EFV = efavirenz; FDA = U.S. Food and Drug Administration; FDC = fixed-dose combination; FTC = emtricitabine; HLA = human leukocyte antigen; INSTI = integrase strand transfer inhibitor; HBV = hepatitis B virus; LPV/r = lopinavir/ritonavir; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; NVP = nevirapine; PI = protease inhibitor; RAL = raltegravir; RTV = ritonavir; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; ZDV = zidovudine

What Not to Start: Regimens Not Recommended for Initial Antiretroviral Therapy in Infants and Children

Table 10. Antiretroviral Regimens or Components That Are Not Recommended for Initial Treatment of HIV Infection in Children and Adolescents

ARV Regimen	Rationale
Regimens containing only NRTIs , such as a single NRTI , two NRTIs , or three NRTIs (including nucleotide RTIs, TDF, TAF)	Inferior virologic efficacy, with high rates of early viral failure
Regimens containing three drug classes	Potential to induce multiclass resistance. Use as an initial regimen in children has not been studied.
Regimens containing three NRTIs and one NNRTI	Added cost and complexity outweigh any benefit
Dual NNRTI combinations	Enhanced toxicity
Dual- PI regimens	Insufficient data to recommend; potential for added toxicities
Oral regimens containing only two ARV drugs	Not FDA approved for pediatric use. For ARV-naïve adolescents ≥ 12 years of age who weigh ≥ 25 kg and meet criteria listed above in Recommended Regimens for Children and Adolescents Aged ≥ 12 Years, a combination of DTG/3TC can be used as an alternate regimen for initial therapy.
Use of TAF/FTC or TDF/FTC with COBI or RTV boosted PIs in children < 35 kg	The COBI or RTV component will also increase tenofovir exposure and no data is available for the use of these combinations
ARV Component	Rationale
Any regimen containing 3TC and FTC	Similar resistance profile and no additive benefit
Any regimen containing TDF and TAF	No data to suggest potentially additive efficacy
Unboosted ATV -containing regimens in children	Inadequate drug exposure
CAB	Not FDA approved for use in individuals who are ARV-naïve or in children aged < 12 years and weighing < 35 kg
DRV/r in children < 3 years	Potential for seizures
Once-daily DRV -based regimens in children aged ≥ 3 years to < 12 years	Insufficient data to recommend
EFV -based regimens for children aged < 3 years	CYP2B6 genotyping required to determine appropriate dosing
ETR -based regimens	Insufficient data to recommend; unlikely to be used as initial therapy

EVG-based regimens	First-generation INSTIs with lower barriers to resistance than second-generation INSTIs (BIC and DTG) that are now available for initial ARV regimens in children
FTR	Not FDA approved for use in adults who are ARV-naïve or for pediatric use
IBA	Not FDA approved for use in adults who are ARV-naïve or for pediatric use
LEN	Not FDA approved for use in adults who are ARV-naïve or for pediatric use
LPV/r dosed once daily	Inadequate drug exposure
MVC-based regimens	Only effective for CCR5-tropic virus
TDF-containing regimens in children aged <2 years	Potential bone toxicity. Appropriate dose has yet to be determined.
NVP as a component of initial ARV regimen in adolescent girls with CD4 count >250 cells/mm ³ and adolescent boys with CD4 count >400 cells/mm ³	Increased incidence of symptomatic (including serious and potentially fatal) hepatic events in the patient group

Key: ARV = antiretroviral; ATV = atazanavir; BIC = bictegravir; CAB = cabotegravir; CYP = cytochrome P450; DRV = darunavir; DRV/r = darunavir/ritonavir; DTG = dolutegravir; EFV = efavirenz; ETR = etravirine; EVG = elvitegravir; FDA = U.S. Food and Drug Administration; FTR = fostemsavir; IBA = ibalizumab; INSTI = integrase strand transfer inhibitor; LEN = lenacapavir; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; PI = protease inhibitor; TDF = tenofovir disoproxil fumarate

4 Detaillierte Darstellung der Recherchestrategie

Cochrane Library - Cochrane Database of Systematic Reviews (Issue 03 of 12, March 2026)
am 09.03.2026

#	Suchschritt
1	[mh "HIV"] OR [mh "HIV Infections"]
2	(hiv*):ti,kw
3	((human) AND (immunodeficiency OR immuno-deficiency OR immunologic deficiency) AND (virus)):ti,kw
4	{OR #1-#3} with Cochrane Library publication date from Mar 2021 to present
5	{OR #1-#3} with Cochrane Library publication date from Mar 2024 to present
6	#4 NOT #5

Leitlinien und systematische Reviews in PubMed am 09.03.2026

verwendete Suchfilter für Leitlinien:

Konsentierter Standardfilter für Leitlinien (LL), Team Informationsmanagement der Abteilung Fachberatung Medizin, Gemeinsamer Bundesausschuss, letzte Aktualisierung am 20.03.2026

verwendeter Suchfilter für systematische Reviews:

Konsentierter Standardfilter für Systematische Reviews (SR), Team Informationsmanagement der Abteilung Fachberatung Medizin, Gemeinsamer Bundesausschuss, letzte Aktualisierung am 01.01.2026.

#	Suchschritt
	Leitlinien
1	"hiv-1"[majr]
2	"hiv infections"[majr]
3	hiv[ti] OR hiv1[ti] OR hivi[ti]
4	human[ti] AND (immunodeficiency[ti] OR immuno-deficiency[ti] OR immunologic deficiency[ti]) AND virus[ti]
5	#1 OR #2 OR #3 OR #4
6	(#5) AND (Guideline[pt] OR Practice Guideline[pt] OR Consensus Statement [pt] OR Consensus Development Conference, NIH[pt] OR guideline*[ti] OR recommendation*[ti])
7	(((((#6) AND ("2021/03/01"[PDAT] : "3000"[PDAT])) NOT ("The Cochrane database of systematic reviews"[Journal]) NOT ((comment[ptyp]) OR letter[ptyp]))) NOT ("retracted publication"[pt] OR "retraction notice"[pt] OR "preprint"[pt])
	systematische Reviews
8	"hiv-1/drug effects"[majr]
9	"hiv infections/therapy"[majr]
10	hiv[tiab] OR hiv1[tiab] OR hivi[tiab]

#	Suchschritt
11	human[tiab] AND (immunodeficiency[tiab] OR immuno-deficiency[tiab] OR immunologic deficiency[tiab]) AND virus[tiab]
12	(#10 OR #11) AND ((treatment*[tiab] OR treating[tiab] OR treated[tiab] OR treat[tiab] OR treats[tiab] OR treatab*[tiab] OR therapy[tiab] OR therapies[tiab] OR therapeutic*[tiab] OR monotherap*[tiab] OR polytherap*[tiab] OR pharmacotherap*[tiab] OR effect*[tiab] OR efficacy[tiab] OR management[tiab] OR drug*[tiab]))
13	#12 NOT medline[sb]
14	#8 OR #9 OR #13
15	(#14) AND ("systematic review"[pt] OR "meta-analysis"[pt] OR "network meta-analysis"[pt] OR (systematic*[tiab] AND (review*[tiab] OR overview*[tiab])) OR metareview*[tiab] OR umbrella review*[tiab] OR "overview of reviews"[tiab] OR meta-analy*[tiab] OR metaanaly*[tiab] OR metanaly*[tiab] OR meta-synthes*[tiab] OR metasynthes*[tiab] OR meta-study[tiab] OR metastudy[tiab] OR integrative review[tiab] OR integrative literature review[tiab] OR evidence review[tiab] OR (("evidence-based medicine"[mh] OR evidence synthes*[tiab]) AND "review"[pt]) OR (((("evidence based"[tiab:~3]) OR evidence base[tiab]) AND (review*[tiab] OR overview*[tiab])) OR (review[ti] AND (comprehensive[ti] OR studies[ti] OR trials[ti])) OR ((critical appraisal*[tiab] OR critically appraise*[tiab] OR study selection[tiab] OR ((predetermined[tiab] OR inclusion[tiab] OR selection[tiab] OR eligibility[tiab]) AND criteri*[tiab]) OR exclusion criteri*[tiab] OR screening criteri*[tiab] OR systematic*[tiab] OR data extraction*[tiab] OR data synthes*[tiab] OR prisma*[tiab] OR moose[tiab] OR entreq[tiab] OR mecir[tiab] OR stard[tiab] OR strobe[tiab] OR "risk of bias"[tiab]) AND (survey*[tiab] OR overview*[tiab] OR review*[tiab] OR search*[tiab] OR analysis[ti] OR apprais*[tiab] OR research*[tiab] OR synthes*[tiab]) AND (literature[tiab] OR articles[tiab] OR publications[tiab] OR bibliographies[tiab] OR published[tiab] OR citations[tiab] OR database*[tiab] OR references[tiab] OR reference-list*[tiab] OR papers[tiab] OR trials[tiab] OR studies[tiab] OR medline[tiab] OR embase[tiab] OR cochrane[tiab] OR pubmed[tiab] OR "web of science" [tiab] OR cinahl[tiab] OR cinhal[tiab] OR scisearch[tiab] OR ovid[tiab] OR ebsco[tiab] OR scopus[tiab] OR epistemonikos[tiab] OR prospero[tiab] OR proquest[tiab] OR lilacs[tiab] OR biosis[tiab])) OR "technical report"[pt] OR HTA[tiab] OR technology assessment*[tiab] OR technology report*[tiab])
16	((#15) AND ("2021/03/01"[PDAT] : "3000"[PDAT]) NOT "The Cochrane database of systematic reviews"[Journal]) NOT ("retracted publication"[pt] OR "retraction notice"[pt] OR "preprint"[pt])
	systematische Reviews ohne Leitlinien
17	(#16) NOT (#7)
18	(#17) AND ("2024/03/01"[PDAT] : "3000"[PDAT])
19	#17 NOT #18

Iterative Handsuche nach grauer Literatur, abgeschlossen am 09.03.2026, überprüft am 06.07.2026

- Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF)
- National Institute for Health and Care Excellence (NICE)
- Scottish Intercollegiate Guideline Network (SIGN)
- World Health Organization (WHO)
- ECRI Guidelines Trust (ECRI)
- Dynamed / EBSCO
- Guidelines International Network (GIN)
- Trip Medical Database

Referenzen

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2. **World Health Organization (WHO).** WHO updated recommendations on HIV clinical management: recommendations for a public health approach [online]. Geneva (SUI): WHO; 2025. [Zugriff: 06.07.2026]. (WHO guidelines approved by the Guidelines Review Committee). URL: <https://www.who.int/publications/i/item/9789240119468https://iris.who.int/handle/10665/384580>.
3. **World Health Organization (WHO).** WHO updated recommendations on HIV clinical management: recommendations for a public health approach: web annex: supporting information [online]. Geneva (SUI): WHO; 2025. [Zugriff: 06.07.2026]. (WHO guidelines approved by the Guidelines Review Committee). URL: <https://iris.who.int/server/api/core/bitstreams/15bfbf7f-9dc6-44fe-8dc5-1beb7be8848b/content>.

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- [A] **Rethlefsen ML, Kirtley S, Waffenschmidt S, Ayala AP, Moher D, Page MJ, et al.** PRISMA-S: an extension to the PRISMA Statement for Reporting Literature Searches in Systematic Reviews. Syst Rev 2021;10(1):39. <https://doi.org/10.1186/s13643-020-01542-z>
- [B] **McGowan J, Sampson M, Salzwedel DM, Cogo E, Foerster V, Lefebvre C.** PRESS Peer Review of Electronic Search Strategies: 2015 Guideline Statement. J Clin Epidemiol 2016;75:40-46. <https://doi.org/10.1016/j.jclinepi.2016.01.021>

**Schriftliche Beteiligung der wissenschaftlich-medizinischen
Fachgesellschaften und der Arzneimittelkommission der
deutschen Ärzteschaft (AkdÄ) zur Bestimmung der
zweckmäßigen Vergleichstherapie nach § 35a SGB V**

- keine eingegangenen schriftlichen Rückmeldungen gem. § 7 Absatz 6 Verfo