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CENTENE[®]
Corporation

Treatment of Human Immunodeficiency Virus (HIV) in Adults

July 2024

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OBJECTIVES

- HIV Overview
- Standard of Care
 - Screening, diagnostics, treatment goals, initiation
 - Pre-exposure prophylaxis (PrEP) & Post-exposure prophylaxis (PEP)
- HIV Medications
- Conclusion

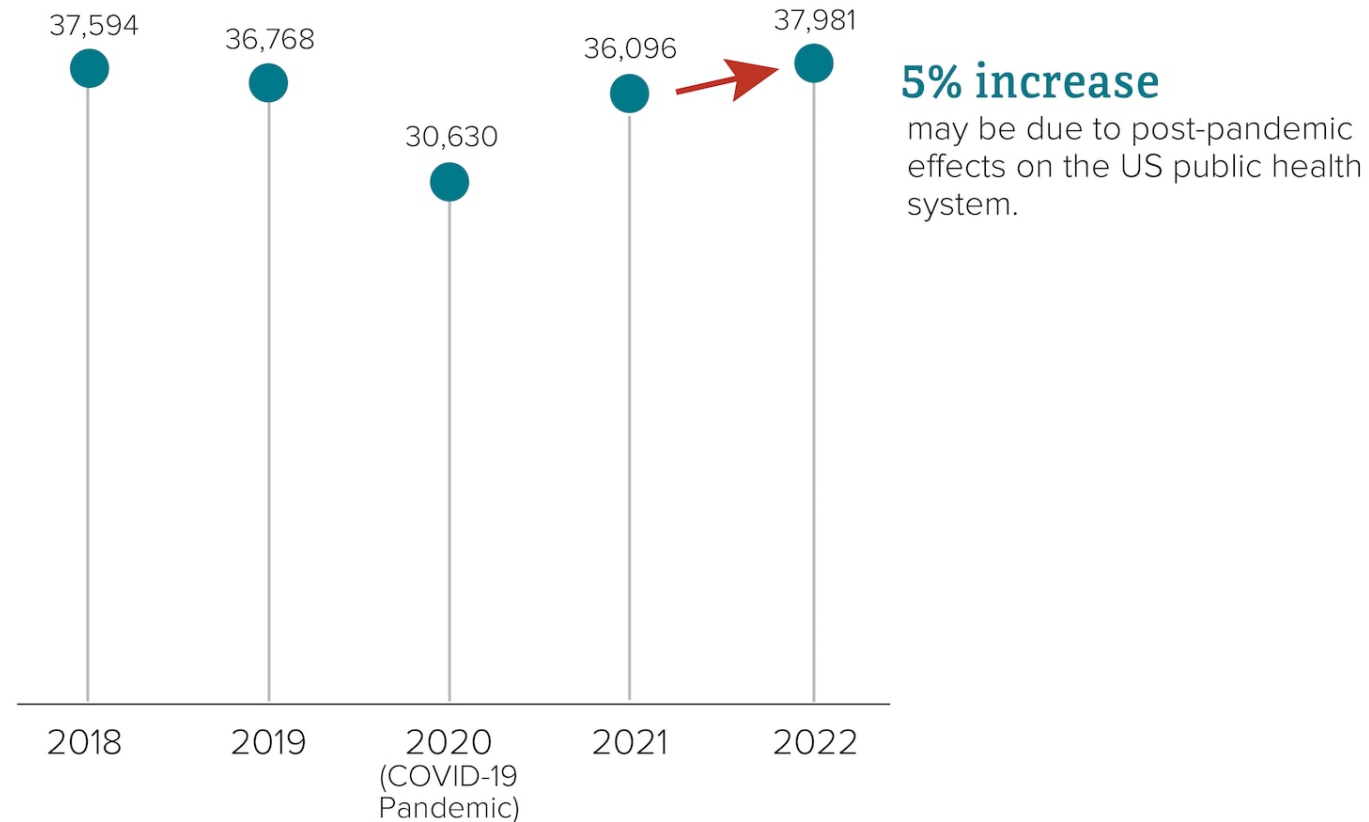


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HIV Overview



EPIDEMIOLOGY



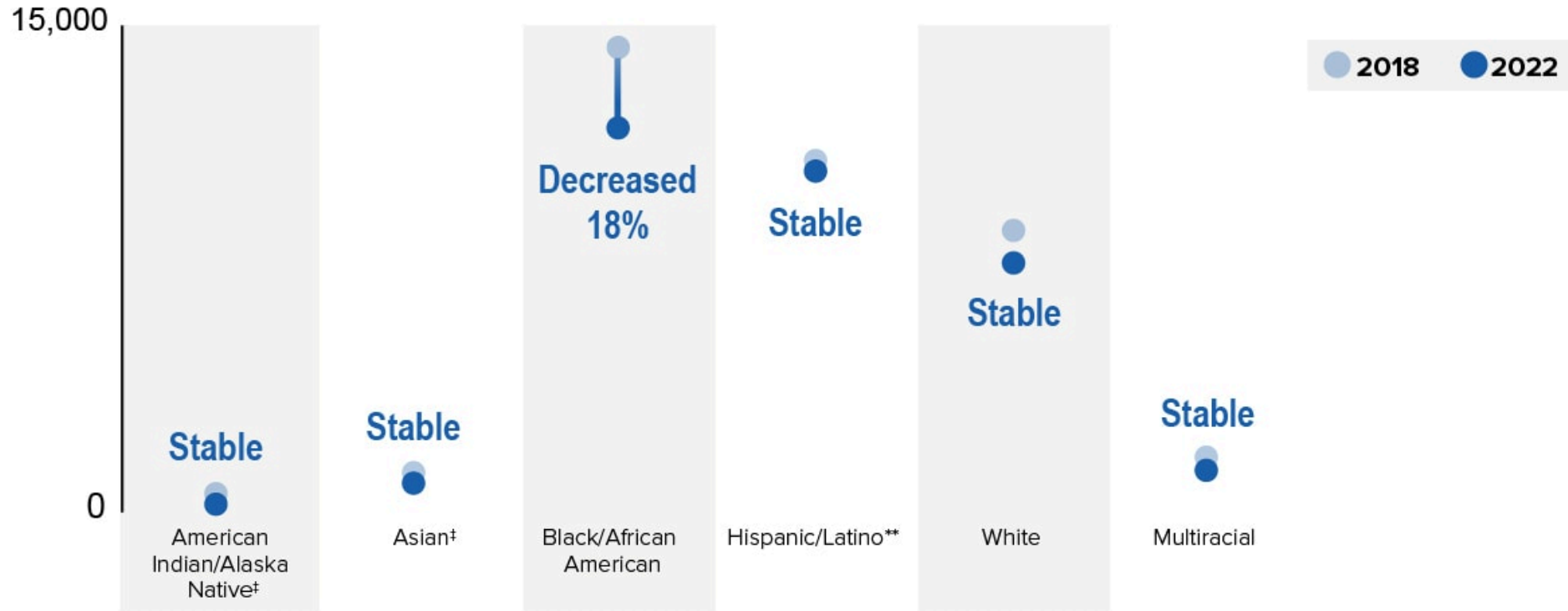
Ending
the
HIV
Epidemic

Overall Goal: Decrease the number of new HIV diagnoses to 9,588 by 2025 and 3,000 by 2030.



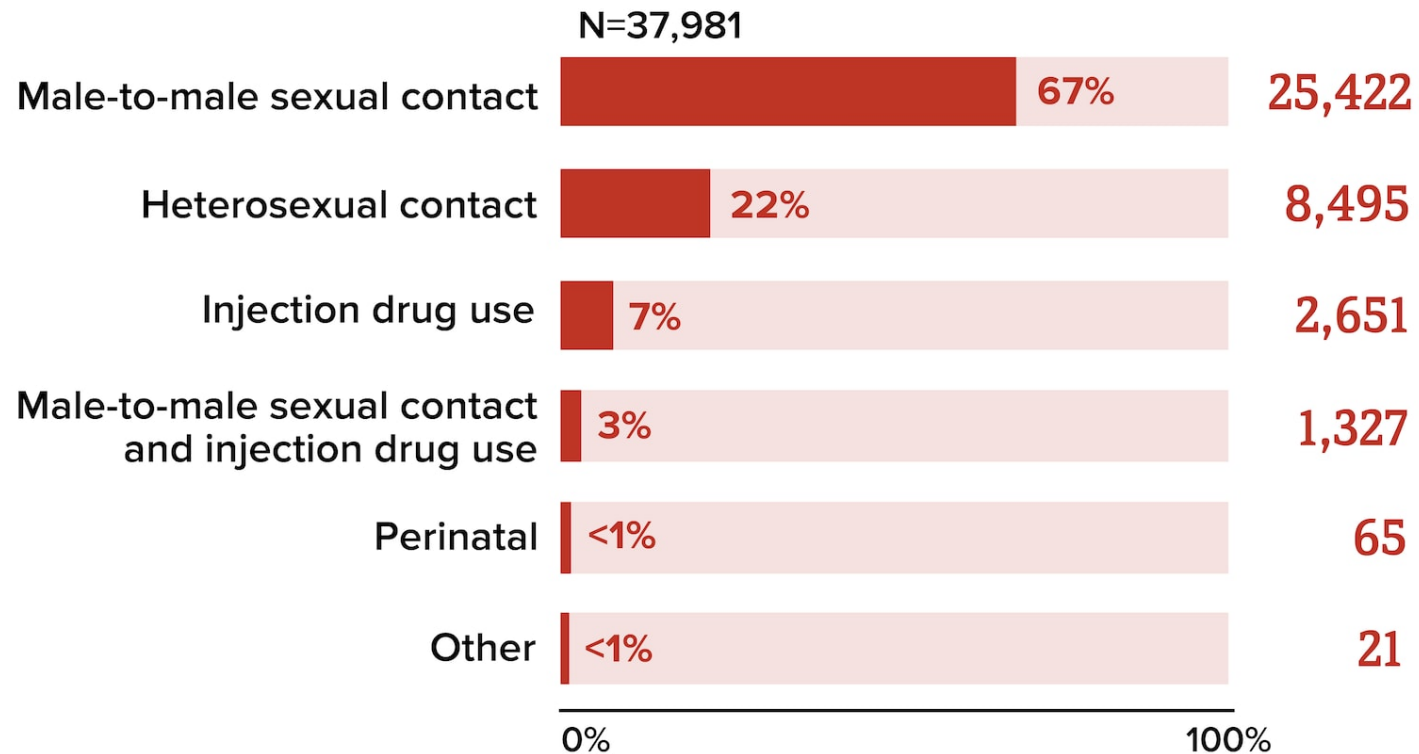
EPIDEMIOLOGY

Estimated HIV infections decreased 18% among Black/African American people. However, racial and ethnic differences persist.

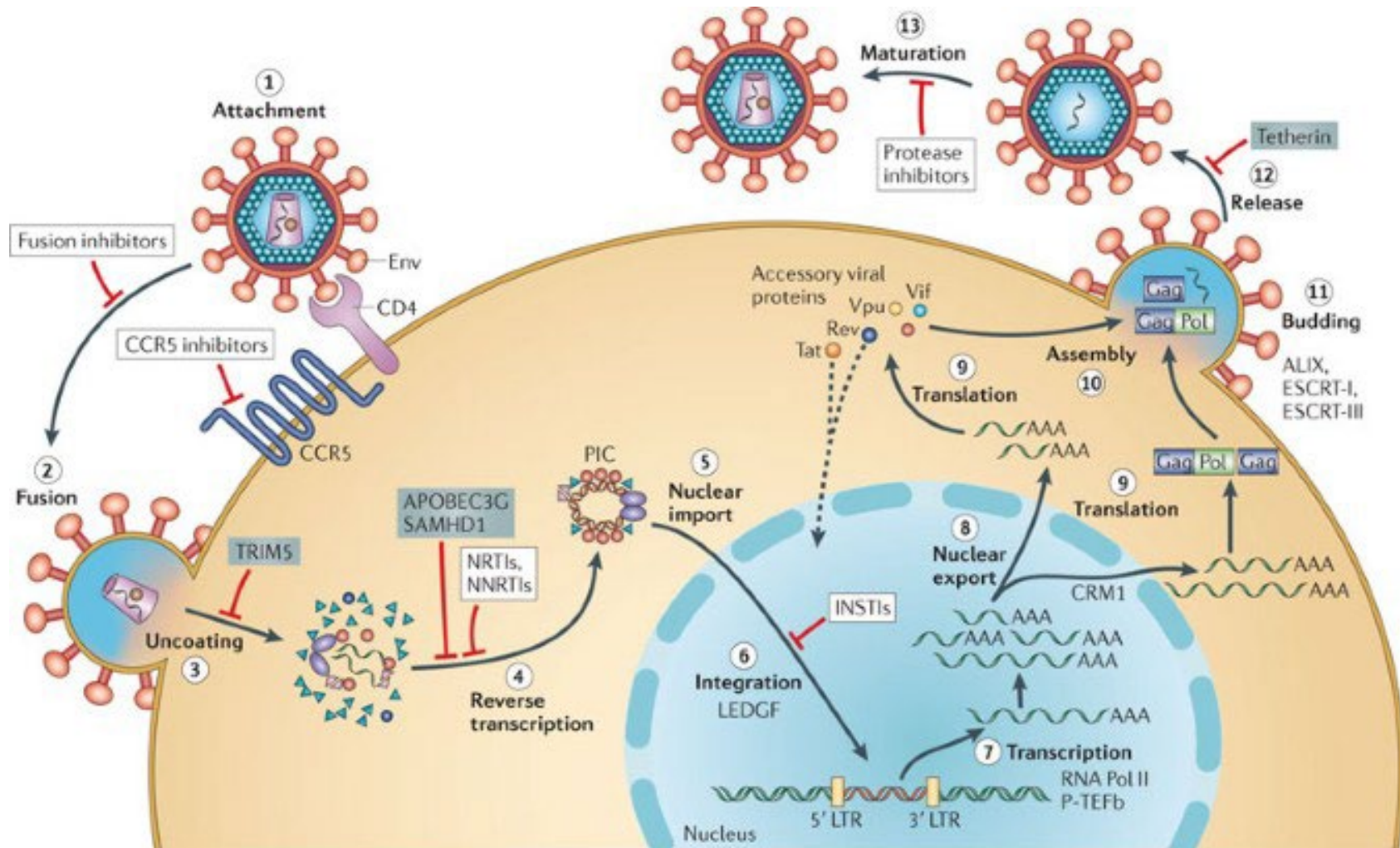


EPIDEMIOLOGY

Gay, bisexual, and other men who reported male-to-male sexual contact are the population most affected by HIV.



HIV LIFE CYCLE & THERAPEUTIC CLASSES



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Standard of Care



SCREENING



Pregnant



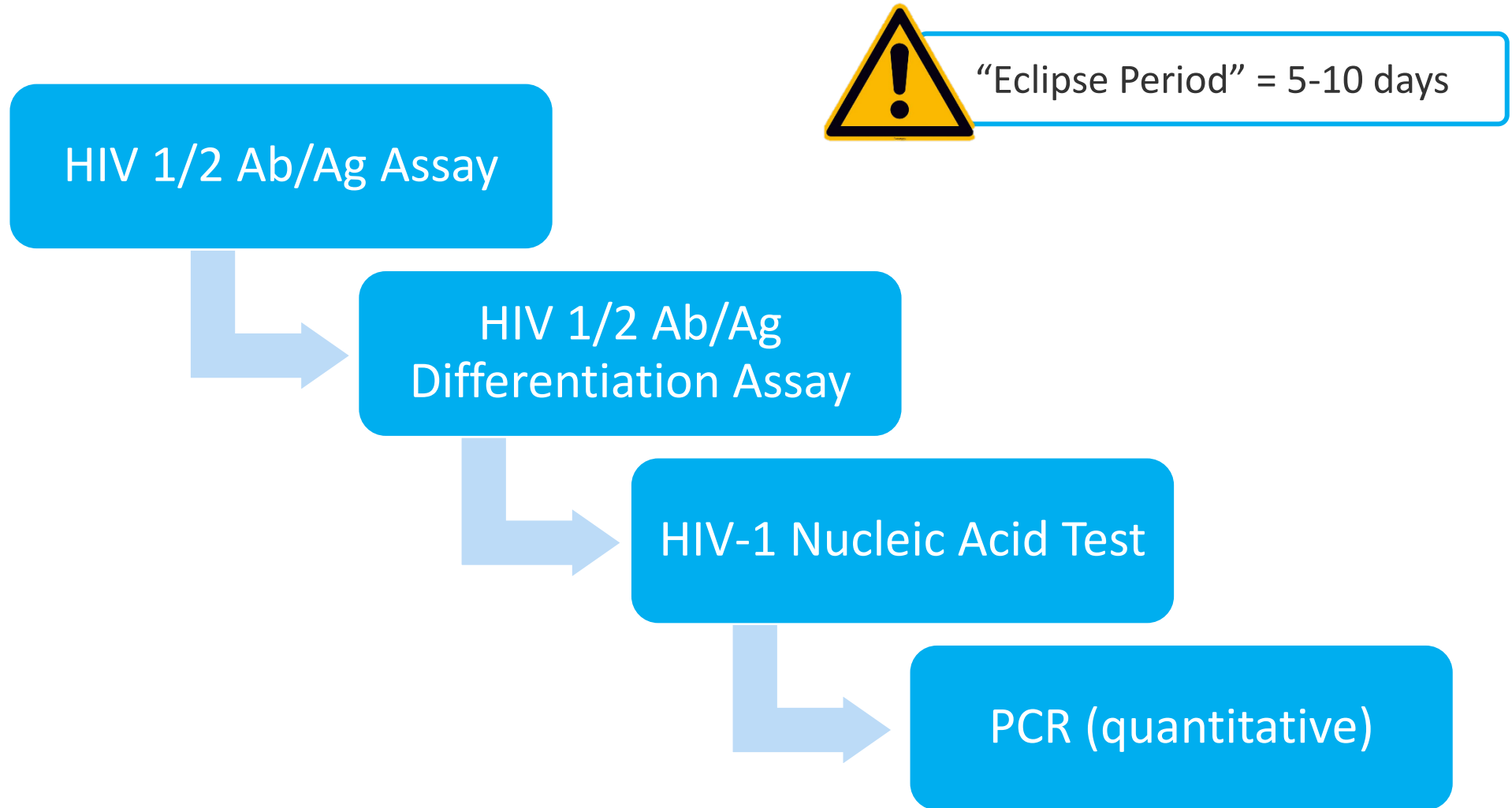
Age 13-64



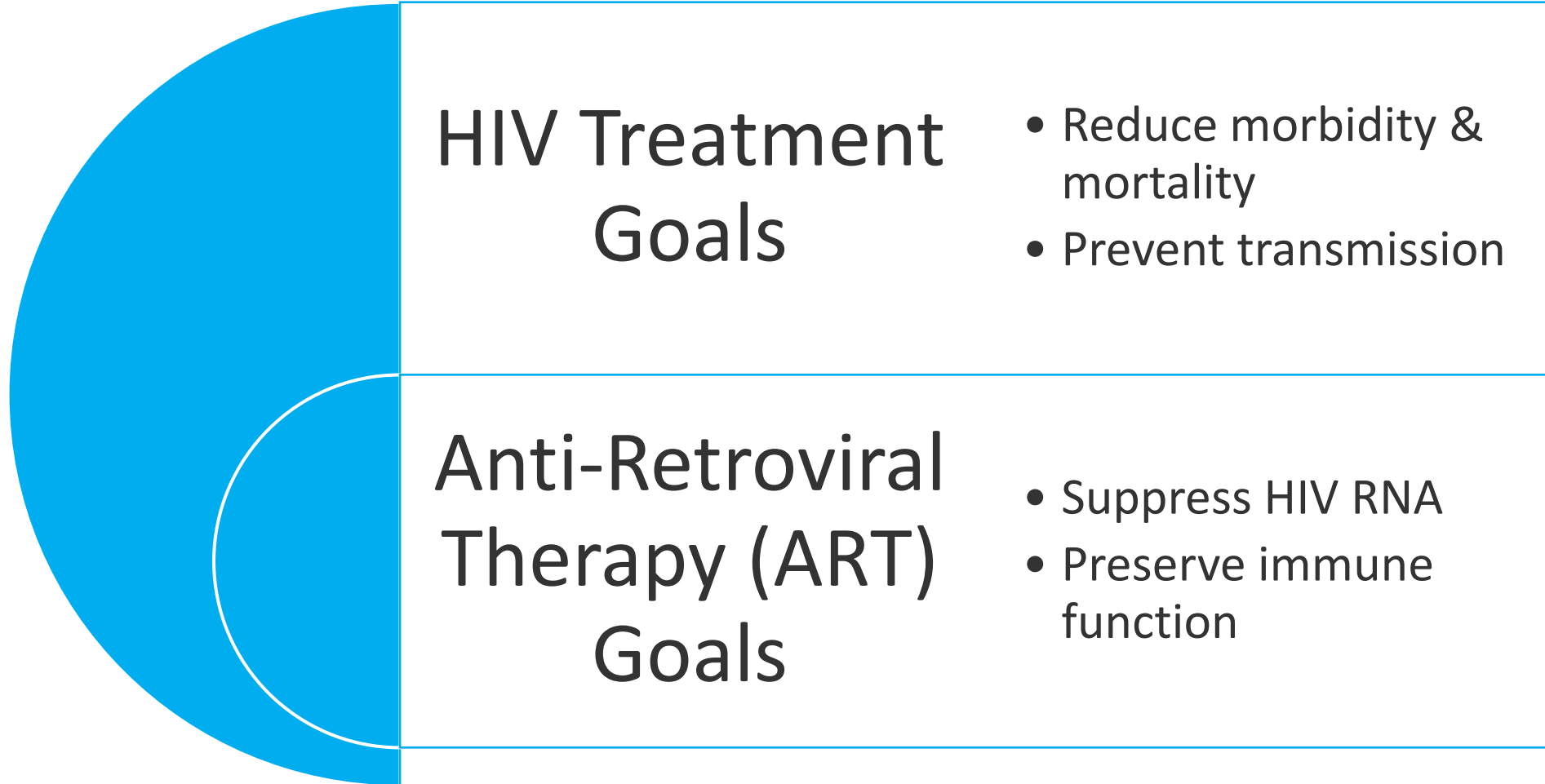
Ongoing risk factors



DIAGNOSTICS



GOALS



U=U



ART INITIATION (TREATMENT-NAÏVE PATIENTS)

Triple Therapy

- 2 NRTI + 1 INSTI
- 2 NRTI + 1 NNRTI
- 2 NRTI + 1 PI

Dual Therapy

- 1 NRTI + 1 INSTI
- 1 NRTI + 1 PI
- 1 INSTI + 1 PI
- 1 NNRTI + 1 INSTI



LABORATORY MONITORING

HIV viral load

CD4 count

HIV resistance

HBV/HCV
serology

Urinalysis

BMP & LFT

CBC

Fasting lipid
panel &
glucose or A1c

HLA-B*5701
for abacavir

Tropism test
for maraviroc



RECENT UPDATES (DHHS 2021-2024)

STATIN THERAPY

- Moderate intensity statin for **age 40-75, ASCVD risk 5-20%**
- Significant reduction (35%) in major adverse CV events with daily pitavastatin in HIV patients aged 40-75 on ART



NEW DRUGS

- Cabotegravir ER for PrEP
- Long-acting Cabotegravir/Rilpivirine IM injection
- Lenacapavir: Capsid inhibitor (new class)

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PrEP & PEP



PRE-EXPOSURE PROPHYLAXIS (PrEP)

Who should
Receive PrEP?

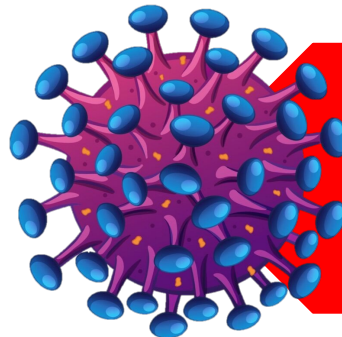
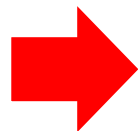


Patients who reports
risky sexual behaviors



Patients who reports
risky injection practices

Who should
not?



Patients with acute and
chronic HIV infection



PrEP: TESTING METHODS

Draw blood → At/Ab test

- Point-of care fingerstick blood test is acceptable

Oral fluid test not acceptable

- Low sensitivity



PrEP: CHOICE OF REGIMEN

Oral Regimen

- MSM* or transgender women
 - Emtricitabine/TDF[◆] or Emtricitabine/TAF[◇] daily
- Heterosexual men and women
 - Emtricitabine/TDF daily
- PWID**
 - Emtricitabine/TDF daily

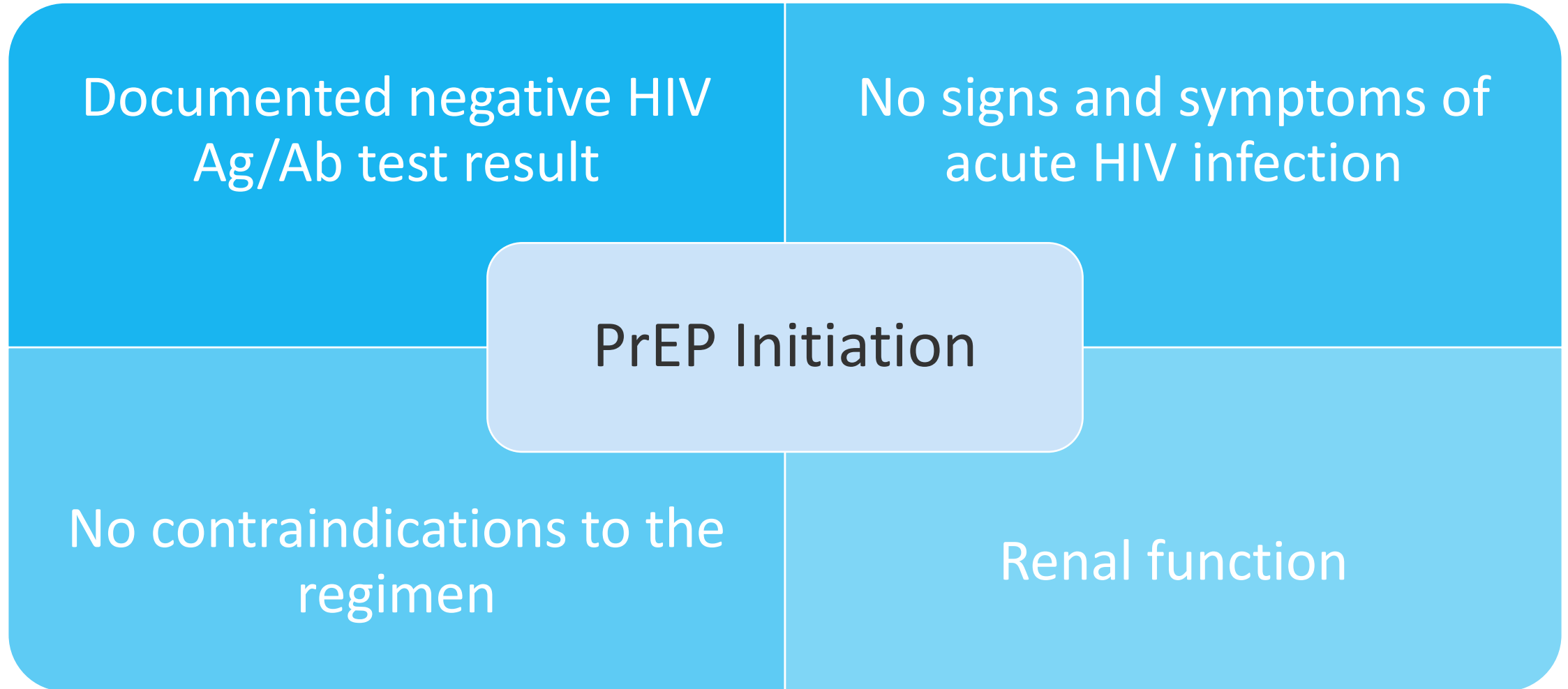
- * MSM: Men who have sex with men
- ** PWID: Persons who inject drug
- ◆ TDF: Tenofovir disoproxil fumarate
- ◇ TAF: Tenofovir alafenamide

Injection Regimen

- All patients who are eligible
 - Cabotegravir ER (Apretude[®])



PrEP: CLINICAL ELIGIBILITY



POST-EXPOSURE PROPHYLAXIS (PEP)

Start within 72 hours

28-day course

Discuss potential
side effects

Do not use abacavir-
based backbone

Preferred regimen:

- Emtricitabine/TDF + raltegravir 400 mg PO **BID**
- Emtricitabine/TDF + dolutegravir 50 mg PO daily

Alternative regimen:

- Emtricitabine/TDF + darunavir 800 mg PO daily + ritonavir 100 mg PO daily



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Medications



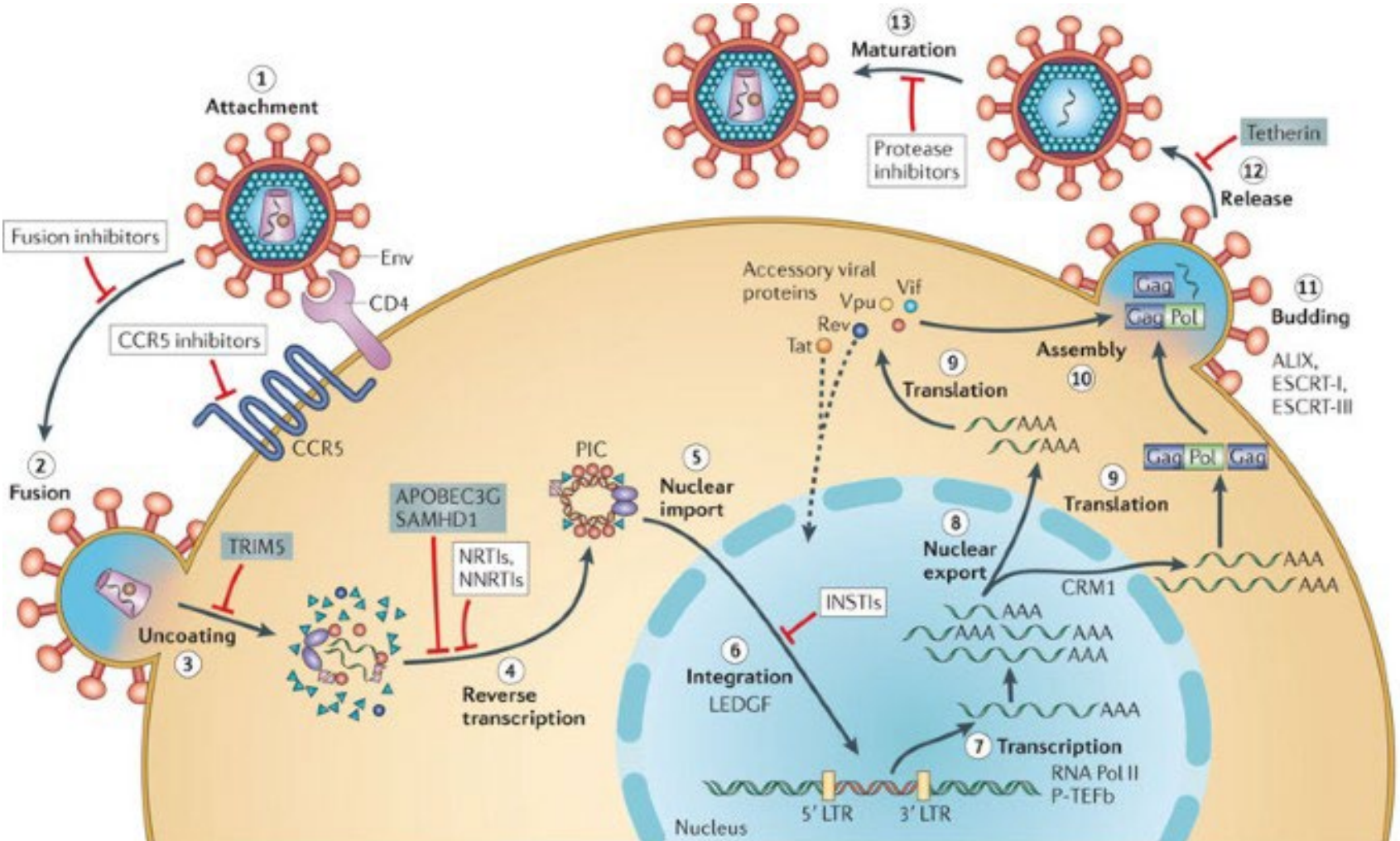
THERAPEUTIC CLASSES

Attachment Inhibitors	Post-Attachment Inhibitors	Fusion Inhibitors	CCR5 Inhibitor	Capsid Inhibitors
Fostemsavir (Rukobia)	Ibalizumab (Trogarzo)	Enfuvirtide (Fuzeon)	Maraviroc (Selzentry)	Lenacapavir (Sunlenca)

NRTIs	NNRTIs	INSTIs	PIs
Abacavir (Ziagen)	Doravirine (Pifeltro)	Elvitegravir	Atazanavir (Reyataz)
Emtricitabine (Emtriva)	Efavirenz (Sustiva)	Raltegravir (Isentress)	Darunavir (Prezista)
Lamivudine (Epivir)	Etravirine (Intelence)	Cabotegravir (Vocabria, Apretude)	Fosamprenavir (Lexiva)
Tenofovir disoproxil fumarate=TDF (Viread)	Nevirapine (Viramune)	Dolutegravir (Tivicay)	Tipranavir (Aptivus)
Tenofovir alafenamide=TAF	Rilpivirine (Edurant)	Bictegravir	PK Booster
Zidovudine (Retrovir)			Cobistat (Tybost)
			Ritonavir (Norvir)*



THERAPEUTIC CLASSES



FIRST-LINE AGENTS

Brands	Regimen	DHHS 2021
Biktarvy®	Bictegravir/emtricitabine/TAF	AI
Triumeq®	Dolutegravir/abacavir/lamivudine	AI
Dovato®	Dolutegravir/lamivudine	AI
Tivicay® + Descovy®	Dolutegravir + emtricitabine/TAF	AI
Tivicay® + Truvada®	Dolutegravir + emtricitabine/TDF	AI
Tivicay® + Cimduo™	Dolutegravir + lamivudine/TDF	AI
Tivicay® + Temixys™	Dolutegravir + lamivudine/TDF	AI



Biktarvy® (Bictegravir/Emtricitabine/TAF)

- **Use:** HIV treatment & PEP
- **Dose:** 50mg/200mg/25mg PO once daily
- **ADEs:** nausea, diarrhea, lactic acidosis, lipid abnormalities, hyperpigmentation, ↑SCr, weight gain, insomnia
- **Black Box Warning:** acute exacerbation of hepatitis B
- **Contraindication:** co-administration with dofetilide or rifampin



Take any time of
the day

No booster
needed

No food
restrictions

Do not use if
CrCl <30mL/min



Triumeq® (Abacavir/Dolutegravir/Lamivudine)

- **Use:** HIV treatment
- **Dose:** 600mg/50mg/300mg PO once daily
- **ADEs:** headache, nausea, diarrhea, fatigue, insomnia, ↑LFTs
- **Black Box Warning:** Hypersensitivity reaction (HSR)
- **Contraindication:** Prior HSR to abacavir, presence of HLA-B*5701 allele, moderate-severe hepatic impairment



Test for HLA-
B*5701

Avoid in patients
with CVD

Do not use if
HBV co-infected

Do not use if CrCl
<30mL/min



Dovato[®] (Dolutegravir/lamivudine)

- **Use:** HIV treatment
- **Dose:** 50mg/300mg PO once daily
- **ADEs:** nausea, diarrhea, weight gain, insomnia
- **Black Box Warning:** Emergence of lamivudine-resistant HBV and exacerbation of Hep B
- **Contraindication:** co-administration with dofetilide

Use only if HIV RNA
≤500,000 copies/mL

Do not use if severe
hepatic impairment

Do not use if HBV
co-infected



Tivicay® (Dolutegravir)

- **Use:** HIV treatment & PEP
- **Dose:** 50mg PO once or twice daily
- **ADEs:** headache, insomnia, weight gain, ↑SCr
- **Black Box Warning:** post-treatment acute exacerbation of hepatitis B
- **Contraindication:** co-administration with dofetilide

Soluble tablet

Do not use if severe hepatic impairment



Truvada[®] (Emtricitabine/TDF)

- **Use:** HIV treatment, PrEP, PEP & HIV/HBV co-infection treatment
- **Dose:** 200mg/300mg PO once daily
- **ADEs:** "NOF", headache, ↑LFTs, abnormal phos levels, ↓neutrophils
- **Black Box Warning:** post-treatment acute exacerbation of hepatitis B, risk of drug resistance (PrEP)

Nephrotoxicity

Osteotoxicity

Fanconi
Syndrome



Descovy® (Emtricitabine/TAF)

- **Use:** HIV treatment & PrEP
- **Dose:** 200mg/25mg PO once daily
- **ADEs:** hyperpigmentation, nausea, diarrhea, weight gain, ↑LFTs
- **Black Box Warning:** acute exacerbation of Hep B, risk of drug resistance (PrEP)

Prodrug of TDF

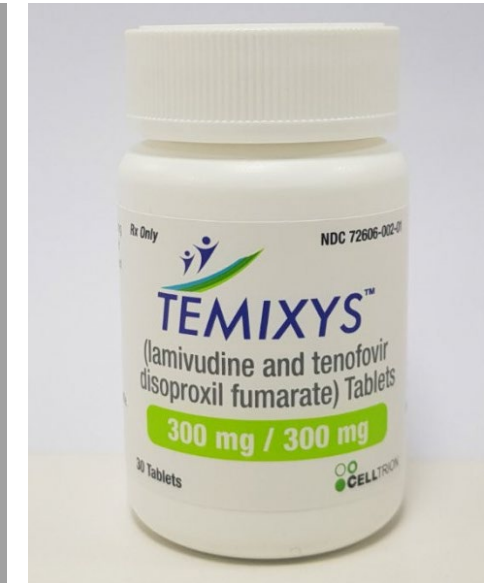
Much less
“NOF”

Do not use if
CrCl <30mL/min



Cimduo™ & Temixys™ (Lamivudine/TDF)

- **Use:** HIV treatment & HIV/HBV co-infection treatment
- **Dose:** 300mg/300mg PO once daily
- **ADEs:** nausea, diarrhea, “NOF”
- **Black Box Warning:** post-treatment acute exacerbation of hepatitis B



Nephrotoxicity

Osteotoxicity

Fanconi
Syndrome



ALTERNATIVES

Brands	Regimen	DHHS 2021
Isentress [®] + Descovy [®]	Raltegravir + emtricitabine/TAF	BII
Isentress [®] + Truvada [®]	Raltegravir + emtricitabine/TDF	BI
Genvoya [®]	Elvitegravir/cobicistat/emtricitabine/TAF	BI
Stribild [®]	Elvitegravir/cobicistat/emtricitabine/TDF	BI
May available generic	Boosted darunavir + emtricitabine/TAF or TDF	A1/BII
May available generic	Boosted darunavir + abacavir/lamivudine	A1/BII
May available generic	Boosted atazanavir + emtricitabine/TAF or TDF	BI
Atripla [®]	Efavirenz/emtricitabine/TAF or TDF	BI/BII
Symfi or Symfi Lo [®]	Efavirenz/lamivudine/TDF	BI/BI
Complera [®]	Rilpivirine/emtricitabine/TAF	BI
Odefsey [®]	Rilpivirine/emtricitabine/TDF	BI



ALTERNATIVES/OPTIMIZATION

Brands	Regimen	DHHS 2021
Delstrigo [®]	Doravirine/lamivudine/TDF	BI
Pifiltero [®] + Descovy [®]	Doravirine + emtricitabine/TAF	BII
Prezista [®] + Norvir [®] + Isentress [®] *	Darunavir/ritonavir + raltegravir BID	CI
Prezista [®] + Norvir [®] + Epivir [®]	Darunavir/ritonavir + lamivudine	CI

Brands	Regimen	Patient must have:
Juluca [®]	Dolutegravir/rilpivirine	<ol style="list-style-type: none"> 1. Already received another ART & achieved undetectable VL 2. No history of resistance to the drug class or treatment failure
Vocabria [®] (PO) Cabenuva [®] (IM)	Cabotegravir + rilpivirine	

*Only if HIV RNA <100,000 copies/mL and CD4 cell count >200 cells/mm³



Cabenuva® (Cabotegravir/Rilpivirine)

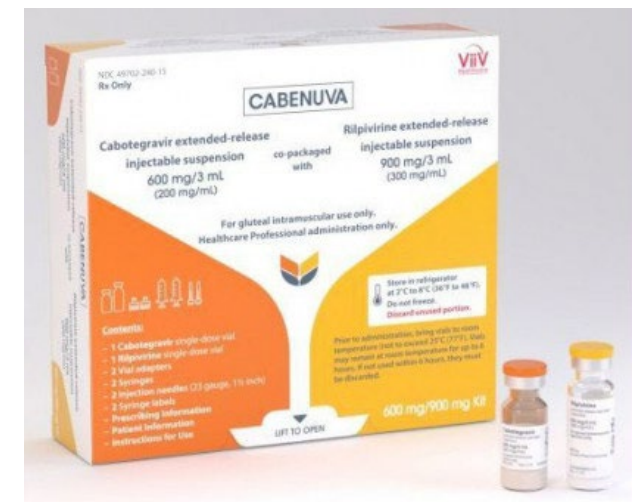
- **Use:** HIV treatment & PEP
- **Dose:** IM once monthly and bimonthly dosing
- **ADEs:** injection site reactions (83%), pyrexia, fatigue, headache

Approved by FDA in
January 2021

Resistance testing

Two vials co-packaged
with supplies

Increase monitoring if
CrCl <15mL/min



Sunlenca[®] (Lenacapavir)

- **Use:** multi-drug resistant HIV treatment
- **Dose:** Two options (PO+ twice yearly SC)
- **ADEs:** injection site reactions (65%), glucosuria, hyperglycemia, proteinuria
- **Warnings:** Immune reconstitution syndrome
- **Contraindication:** Co-administration with strong CYP3A inducers



Approved by FDA
in December 2022

First-in-class

Treats multi-drug
resistant HIV



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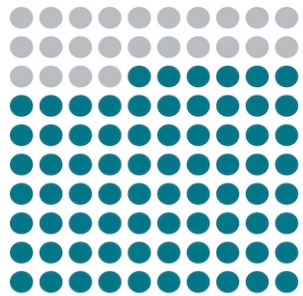
Conclusion



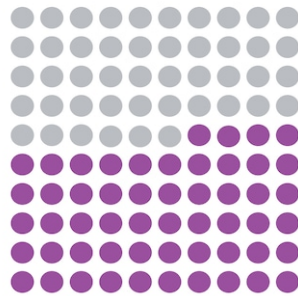
CHALLENGES

Challenges, including structural barriers such as housing instability, poverty, or transportation access, may prevent people from getting and staying in HIV care.

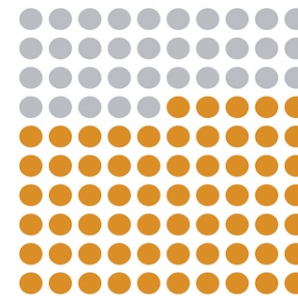
For every 100 people with diagnosed HIV in 2022:



76
received
some
HIV care[†]



54
were
retained
in care[‡]



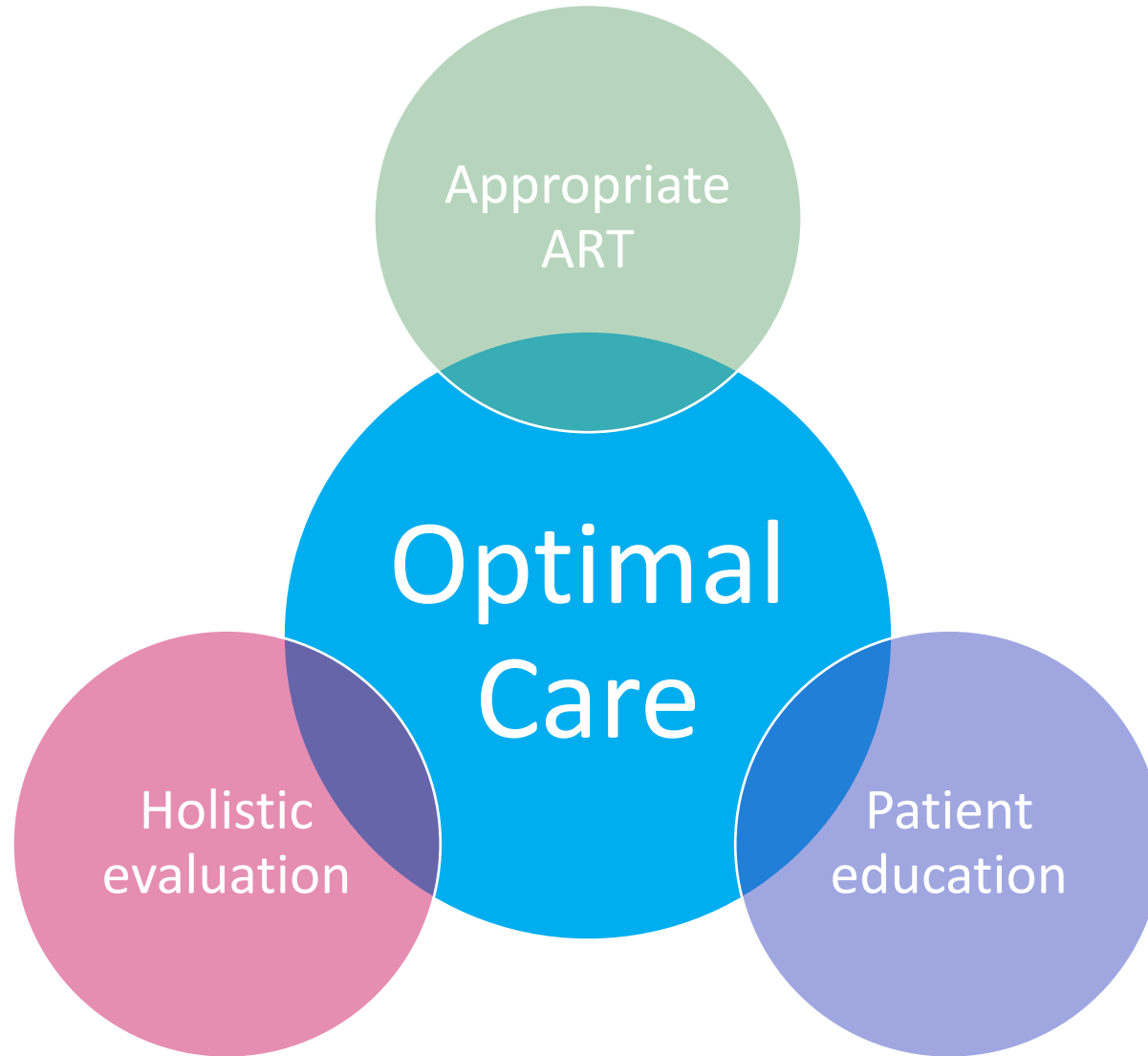
65
were virally
suppressed^{**}

| Ending
| the
| HIV
| Epidemic

Overall Goal: Increase the percentage of people with diagnosed HIV who are virally suppressed to at least 95% by 2025 and remain at 95% by 2030.



CONCLUSION



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Questions?

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APPENDIX: RESOURCES

- HIV drug resistance database
- CDC database
- DHHS guidelines
- National Perinatal Hotline: 1-888-448-8765

APPENDIX: ABBREVIATIONS

- NRTI: Nucleotide Reverse Transcriptase Inhibitor = “nuke”
- NNRTI: Non-Nucleotide Reverse Transcriptase Inhibitor = “non-nuke”
- INSTI: Integrase Strand Transfer Inhibitor = “integrase inhibitor”
- PI: Protease Inhibitor
- Ab/Ag: Antibody-Antigen
- ADE: Adverse Event
- DHHS: Department of Health & Human Services