

Dolutegravir for HIV in newborns: A new option for an urgent need

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Treating HIV in newborns presents a unique challenge, demanding therapies that are both effective against a rapidly replicating virus and safe for a developing physiology. Early diagnosis and prompt initiation of antiretroviral therapy (ART) are critical for preventing disease progression and improving long-term outcomes in this vulnerable population. The recent regulatory action for dolutegravir offers a new option for clinicians managing perinatally acquired HIV.

KEY TAKEAWAYS

- **The Pivot:** Dolutegravir is now approved for newborns with HIV, expanding treatment options for the youngest patients.
- **The Data:** The approval is based on pharmacokinetic and safety data in paediatric populations, demonstrating appropriate dosing and tolerability.
- **The Action:** Clinicians have an additional integrase inhibitor for initial ART regimens in neonates and infants.

Perinatal HIV transmission, while significantly reduced in many regions due to effective maternal screening and ART during pregnancy, remains a concern globally. Infants born with HIV face a rapid progression of the disease without immediate and effective treatment. Standard-of-care regimens for neonates typically involve a combination of antiretroviral drugs, often initiated within hours or days of birth, highlighting the urgency of having well-studied and accessible options.

Dolutegravir is an integrase strand transfer inhibitor (INSTI) that blocks HIV replication by preventing the integration of viral DNA into the host cell genome. It has been a cornerstone of adult and older paediatric ART regimens for years due to its potency, favourable resistance profile, and generally good tolerability. The recent approval extends its use to newborns and infants aged at least 4 weeks and weighing at least 3 kg, and for infants and children aged 4 weeks to less than 6 months and weighing at least 3 kg to less than 6 kg, when used in combination with other antiretroviral agents. For a broader overview of managing infectious diseases, the Oxford Handbook of Infectious Diseases and Microbiology provides a comprehensive reference.

Expanding the Treatment Armamentarium

The regulatory decision for dolutegravir in this youngest age group is based on pharmacokinetic and safety data collected in paediatric studies. These studies aimed to establish appropriate dosing to achieve drug exposures comparable to those known to be effective and safe in adults, while accounting for the unique metabolic characteristics of neonates and infants.

Establishing these parameters is important for patient safety, as drug metabolism and distribution can vary significantly in early life, necessitating careful dose adjustments to avoid under-dosing or toxicity.

The availability of dolutegravir for newborns adds a potent INSTI to the limited formulary suitable for this age group. INSTIs are generally preferred in initial ART regimens due to their rapid viral suppression and high barrier to resistance. This is particularly important in newborns, where achieving rapid viral load reduction is paramount to preserving immune function and preventing opportunistic infections. The approval provides clinicians with greater flexibility in constructing optimal ART regimens, especially in settings where specific drug formulations or combinations may be challenging to access or administer.

The Challenge of Adherence and Long-Term Management

Administering ART to newborns and infants presents practical challenges beyond drug efficacy and safety. Palatability of liquid formulations, precise dosing for very small body weights, and the need for consistent adherence by caregivers are significant hurdles. Simplification of regimens, such as once-daily dosing, can improve adherence, which is a critical factor in preventing the development of drug resistance and ensuring long-term treatment success. The ongoing efforts to address HIV action plans highlight the systemic challenges in delivering care.

Still, the long-term implications of early ART exposure, including potential effects on growth, development, and metabolic health, require ongoing monitoring. While dolutegravir has a generally favourable safety profile in older populations, vigilance for any unique adverse events in newborns is essential. This includes careful assessment of potential drug-drug interactions, especially when co-administering other medications common in neonates. The global context of HIV care, including funding challenges, means that new approvals must be accompanied by efforts to ensure equitable access.

The approval of dolutegravir for newborns with HIV is a welcome development, offering a potent and well-characterized antiretroviral option for a patient population with urgent needs. It reflects the continued commitment to developing paediatric formulations and generating the necessary data to support their use. The next step involves ensuring that this new option is integrated effectively into clinical practice guidelines and made accessible to all infants who could benefit, particularly in resource-limited settings where the burden of perinatal HIV remains highest.

CLINICAL IMPLICATIONS

The expanded approval of dolutegravir for newborns with HIV is a practical gain for clinicians. It provides another potent integrase inhibitor for initial ART regimens, which are critical to initiate within days of birth. This broadens the options beyond existing non-nucleoside reverse transcriptase inhibitors and protease inhibitors, offering more flexibility in tailoring treatment to individual patient needs and local drug availability.

For paediatric infectious disease specialists, this means a more robust toolkit for managing perinatally acquired HIV. The established efficacy and tolerability profile of dolutegravir in older children and adults provides a degree of confidence, but careful monitoring for any unique adverse events in neonates remains paramount. The pharmacokinetic data supporting this approval are essential, as dosing in this age group is notoriously challenging.

The pharmaceutical industry's continued investment in paediatric formulations, even for conditions with declining incidence in some regions, is commendable. It underscores the ethical imperative to ensure that

the youngest patients have access to the best available therapies. But, the challenge now shifts to ensuring equitable access globally, particularly in areas with high rates of perinatal HIV transmission, where drug cost and supply chain logistics can be significant barriers.

This approval reinforces the importance of early diagnosis and rapid treatment initiation in newborns with HIV. It empowers clinicians with another effective weapon against a devastating disease, allowing them to achieve viral suppression faster and improve the long-term prognosis for these vulnerable infants.

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