

Heat Stable Carbetocin for prevention of PPH

The case to include on the
NURHT List

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GENERAL MEMBERSHIP MEETING

— of the —

**REPRODUCTIVE HEALTH
SUPPLIES COALITION**

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Approved Product



- HSC is a new formulation of the existing carbetocin molecule
- Carbetocin first approved in 1997
- Carbetocin registered in 70 countries
- Heat-stable carbetocin (HSC) is registered in 27+ countries
- Carbetocin (including new formulation) used in over 8 million women

WHO Trial



- WHO trial to demonstrate efficacy in PPH prevention following vaginal delivery (IM)
- 30,000 patients to be recruited - 11,582 already completed.
- Will be completed within 12 months

Stability



- Product has data on heat stability as follows:
 - 30 degrees – 48 months (4 years)
 - 40 degrees – 6 months
 - 50 degrees – 9 weeks
- Product is ICH Zone IVA and B stable – hot and humid climates.
- Does not require any cold chain or storage.

Unique partnership



- Product is currently available for high price in rich countries
- Will be made available in LMICs in a public-private partnership with
 - WHO
 - Merck for Mothers
 - Ferring
 - Concept Foundation

Potential application in LMICs



- Heat stable
 - Appropriate for settings where sustained cold storage is not feasible
- Single dose
 - Appropriate for settings where intensive monitoring of woman after birth is difficult
- Quality assured
 - Only quality assured product to be made available
- Most appropriate for births attended by Qualified Birth Attendants, by injection

New? Underused?



NEW

- Existing product – new formulation, new indication – specifically adapted to LMICs

UNDERUSED

- Safe, tested, approved, registered and available BUT ONLY in higher income countries
- Not available in LMICs because of restricted indication, higher price and current manufacturing arrangements

Need listing on NURHT now to expedite availability in LMICs.