

Pregnancy Pre-delivery (Adult)

General Instructions

Pre-delivery visits are to occur once during the first or second trimester (pre-delivery visit 1) and once on or after 28 weeks gestation (pre-delivery visit 2). When possible, pregnancy pre-delivery visits should be scheduled in conjunction with the routine cohort protocol visits.

If the pregnancy pre-delivery evaluation is performed in conjunction with a routine cohort protocol visit, the Pregnancy Pre-delivery form is not completed as the necessary information will be captured on the applicable cohort protocol evaluation form.

If the pregnancy pre-delivery evaluation is not performed in conjunction with a routine cohort protocol visit, the Pregnancy Pre-delivery form should be completed along with the Special Visit form, indicating that the primary reason for the special visit is for pregnancy, pre-delivery.

This form captures treatment for hepatitis B received since the last protocol visit. The information is obtained from patient interview and medical record review. When information in the medical record conflicts with information provided by the patient, the medical record is normally considered to be the accurate source, although there may be instances when the information provided by the patient is more up to date or accurate. In this instance, the information provided by the patient may be used.

The coordinator is responsible for obtaining the information captured on this form. In non-English speaking patients, the interview may be performed through a certified interpreter. While a trained translator is preferred, a family member or friend of the patient (who speaks fluent English and the native language of the patient) may be acceptable for this role, as determined on an individual basis.

Specific Instructions

Patient ID: Record the Patient ID in the top right hand corner.

Date of Evaluation: Record the date (month/day/year) that corresponds to the evaluation visit.

Timepoint: Record the protocol timepoint that corresponds to the visit.

Section I: Treatment

Current Treatment: Check "Yes" or "No" to indicate if the patient has received treatment for hepatitis B since the last protocol visit, either interferon or an antiviral oral agent.

If Yes, record each treatment the patient received with the following information.

Antiviral therapy: Record the appropriate code for the treatment.

Note: Tenofovir (TDF) = Tenofovir disoproxil fumarate

Tenofovir (TAF) = tenofovir alafenamide fumarate

<u>Date started</u>: Record the month, day, and two digit year that the treatment was started. If any piece of the date is not known, record "Unk".

<u>Date stopped</u>: Record the month, day, and two digit year that the treatment was stopped. If any piece of the date is not known, record "Unk". If the patient is currently on this treatment, do not complete the date stopped fields and check

"Currently on Therapy".