Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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List of investigators

Acknowledgments

The authors thank the patients and their families for their support and dedication, and investigators and research staff at all study sites.

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Full study inclusion and exclusion criteria

Inclusion Criteria

Signed Written Informed Consent

- Freely given informed consent must be obtained from all subjects prior to clinical trial participation, including informed consent for any screening procedures conducted to establish eligibility for the study.

Target Population

- Able to understand and agree to comply with the prescribed dosing regimens and procedures, report for regularly scheduled study visits, and reliably communicate with study personnel about adverse events and concomitant medications.

- Chronically infected with HCV genotypes 1, 2, 3, 4, 5 or 6, as documented by positive HCV RNA at screening and either
  - Positive anti-HCV antibody, HCV RNA, or a positive HCV genotype test at least 6 months prior to screening; or
  - Liver biopsy consistent with chronic HCV infection.

- Treatment-naive subjects only: mixed, indeterminate, or other variants or genotype 1 (e.g., non-1a and non-1b) were NOT eligible.

- HCV treatment-naive or HCV treatment-experienced with the following restrictions:
  - Treatment-naive:
    - No previous exposure to any interferon formulation (i.e., IFNα, peg-IFNα) or RBV
    - No previous exposure to any HCV direct acting antivirals (DAAs).
  - Treatment-experienced:
    - All permitted prior anti-HCV therapies be discontinued or completed at least 12 weeks prior to screening
    - Previous exposure to NS5A inhibitors is prohibited.
    - Previous treatment with IFNα, with or without RBV is permitted. Documentation of prior virologic response to treatment is desirable but not strictly required. Subjects who did not complete treatment due to laboratory abnormality or intolerable side effect are eligible.
    - Previous exposure to NS3 protease inhibitors including, but not limited to, telaprevir or boceprevir is permitted. Subjects who did not complete
treatment due to laboratory abnormality or intolerable side effects are eligible.

- Previous exposure to nucleoside/nucleotide and non-nucleoside inhibitors of NS5B is permitted (including sofosbuvir [SOF]). Subjects who discontinued previous treatment with SOF due to intolerance of this drug are excluded.

- Previous exposure to other classes of anti-HCV agents (e.g. cyclophilin inhibitors and inhibitors of microRNA) is permitted.

- An HCV RNA at least \(10^4\) IU/mL (10,000 IU/mL) at screening

- HIV-1 infected and either receiving or not receiving combination antiretroviral therapy (cART)
  - **Subjects receiving cART:**
    - Screening HIV RNA < 50 copies/mL and < 200 copies/mL for at least 8 weeks prior to screening
    - Screening CD4 cell count \(\geq 100\) cells/\(\mu\)L
  - **Subjects not receiving cART:**
    - Screening CD4 cell count must be \(\geq 350\) cells/\(\mu\)L

- Seronegative for HBsAg

- Body Mass Index (BMI) of 18 to 35 kg/m\(^2\), inclusive at screening.

- Subjects with compensated cirrhosis are eligible
  - Determination of cirrhosis status is required prior to randomization. Up to 50% of subjects in each of the 12-week treatment arms (HCV treatment-naive and -experienced subjects) and in the 8-week arm (HCV treatment-naive only) may be cirrhotic. A biopsy is not needed for participation in this study, however;
    - A subject will be considered “cirrhotic” if they meet the following criteria:
      - Liver biopsy showing cirrhosis (i.e. Metavir > F3, Ishak > 4 or the equivalent) at any time prior to screening OR;
      - FibroScan showing cirrhosis or results >14.6 kPa within 1 year of Baseline OR;
      - A FibroTest score of \(\geq 0.75\) and an aspartate aminotransferase (AST): platelet ratio index (APRI) of > 2 (performed during Screening).
    - A subject will be considered “non-cirrhotic” if they meet the following criteria:
• Most recent liver biopsy (within ≤36 months of Screening) showing absence of cirrhosis (i.e. Metavir F0-F3, Ishak 0-4, or the equivalent) OR;

• FibroScan with a result of ≤ 9.6 kPa within 1 year of Baseline/Day 1 OR;

• A FibroTest score of ≤ 0.48 and APRI of ≤ 1 (performed during Screening)

  ▪ If a subject is evaluated by more than one testing method which provide conflicting determinations of the subject’s liver status, the determination of cirrhosis will be made using the following methodology:

    • Liver biopsies (performed within the pre-specified timeframe outlined above) take precedence over either FibroScan or FibroTest/APRI.

    • In the absence of an acceptable liver biopsy, FibroScan (performed within the pre-specified timeframe outlined above) results take precedence over FibroTest/APRI.

    • The combined screening FibroTest/APRI results are adequate for enrollment and to determine cirrhosis status if an acceptable biopsy or FibroScan are not available.

    • Note If results from both FibroScan and FibroTest/APRI, do not meet the criteria above defining the subject as “cirrhotic” or “non-cirrhotic”, the subject is considered to have an “indeterminant” liver status and a liver biopsy will be required prior to Day 1 for study participation.

• Subject re-enrollment: This study permits the re-enrollment of a subject that has discontinued the study as a pre-treatment failure (i.e. subject has not been randomized or has not been treated). Discussion with the BMS Medical Monitor must occur prior to subject re-enrollment. If re-enrolled, the subject must be re-consented.

### Age and Reproductive Status

• Males and females ≥ 18 years of age

• Women of childbearing potential (WOCBP) must have a negative serum or urine pregnancy test (minimum sensitivity 25 IU/L or equivalent units of HCG) within 24 hours prior to the start of study drug.

• Women must not be breastfeeding.

• WOCBP must agree to follow instructions for method(s) of contraception for the duration of treatment with DCV and SOF plus 5 half-lives of study drugs (5 days) plus 30 days (duration of ovulatory cycle) for a total of 5 weeks post-treatment completion.
• Men who are sexually active with WOCBP must agree to follow instructions for method(s) of contraception for the duration of treatment with study drugs plus 5 half-lives of the study drug (5 days) plus 90 days (duration of sperm turnover) for a total of 14 weeks post-treatment completion.

• Investigators shall counsel WOCBP and male subjects who are sexually active with WOCBP on the importance of pregnancy prevention and the implications of an unexpected pregnancy. Investigators shall advise WOCBP and male subjects who are sexually active with WOCBP on the use of highly effective methods of contraception. Highly effective methods of contraception have a failure rate of < 1% per year when used consistently and correctly.

• At a minimum, subjects must agree to the use of two methods of contraception, with one method being highly effective and the other method being either highly effective or less effective as listed below:

  o Highly Effective Methods of Contraception
    ▪ Male condoms with spermicide.

    ▪ Hormonal methods of contraception including combined oral contraceptive pills, vaginal ring, injectables, implants, and intrauterine devices (IUDs) such as Mirena® by male subject’s WOCBP partner. Female partners of male subjects participating in the study may use hormone based contraceptives as one of the acceptable methods of contraception since they will not be receiving study drug.

    ▪ WOCBP cannot use hormonal contraception as one of the two methods of contraception because there are no data on the effectiveness of systemic hormonal contraceptives in women taking SOF. However, WOCBP can continue to use hormonal contraceptives, if necessary, in addition to 2 other non-hormonal methods of contraception.

    ▪ Nonhormonal IUDs, such as ParaGard®

    ▪ Tubal Ligation

    ▪ Vasectomy

    ▪ Complete Abstinence

    ▪ Defined as complete avoidance of heterosexual intercourse, and is an acceptable form of contraception for all study drugs. Subjects who choose complete abstinence are not required to use a second method of contraception, but female subjects must continue to have pregnancy tests. Acceptable alternate methods of highly effective contraception must be discussed in the event that the subject chooses to forego complete abstinence.
Less Effective Methods of Contraception

- Diaphragm with spermicide
- Cervical cap with spermicide
- Vaginal sponge
- Male condom without spermicide
- Progestin only pills
- Female condom
  - A male and female condom must not be used together

- Azoospermic males, women who are not of childbearing potential and WOCBP who abstain from heterosexual activity on a continuous basis, are exempt from contraceptive requirements. However, WOCBP who abstain from heterosexual activity on a continuous basis must still undergo pregnancy testing.

Exclusion Criteria

Target Disease Exceptions
- Presence of AIDS-defining opportunistic infections (as defined by the Centers for Disease Control) within 12 weeks prior to study entry.
- Subjects infected with HIV-2.

Medical History and Concurrent Diseases
- Liver or any other organ transplant (including hematopoietic stem cell transplants) other than cornea and hair
- Current or known history of cancer (except in situ carcinoma of the cervix or adequately treated basal or squamous cell carcinoma of the skin) within 5 years prior to screening
- Documented or suspected HCC, as evidenced by previously obtained imaging studies or liver biopsy (or on a screening imaging study/liver biopsy if this was performed)
- Evidence of decompensated liver disease including, but not limited to, radiologic criteria, a history or presence of ascites, bleeding varices, or hepatic encephalopathy
- Evidence of an ongoing medical condition contributing to chronic liver disease other than HCV (such as, but not limited to, hemochromatosis, autoimmune hepatitis, metabolic liver disease, alcoholic liver disease, toxin exposures)
- History of chronic hepatitis B virus (HBV) as documented by HBV serologies (e.g., HBsAg-seropositive). Subjects with resolved HBV infection may participate (e.g., HBsAb-seropositive with concurrent HBsAg-seronegative)
o Any gastrointestinal disease or surgical procedure that may impact the absorption of study drug (subjects who have had cholecystectomy are permitted to enter the study).

o Known history of genetic coagulopathy including, but not limited to, hemophilia

o Uncontrolled diabetes (any subject with a confirmed screening HgA1c ≥ 8.5 must be excluded)

o Confirmed, uncontrolled hypertension (any screening systolic blood pressure ≥ 160 mmHg or diastolic blood pressure ≥ 100 mmHg should be excluded unless discussed with the BMS medical monitor)

o Active substance abuse as defined by DSM-IV, Diagnostic Criteria for Drug and Alcohol Abuse, which in the opinion of the investigator would make the candidate inappropriate for participation in this study

o Active severe psychiatric disorders including but not limited to, schizophrenia, psychosis, bipolar disorder, post-traumatic stress disorder, mania, etc.

o Inability to tolerate oral medication

o Poor venous access that would impair the subject’s ability to comply with the study protocol

**Physical and Laboratory Test Findings**

o Alanine aminotransferase (ALT) ≥10x ULN

o Total Bilirubin ≥ 2 mg/dL (≥ 34 µmol/L), unless due to atazanavir-ritonavir treatment or a history of Gilbert’s disease

o Albumin < 3.0 g/dL (30 g/L)

o Platelets < 50 x 10³ cells/L

o ANC < 0.75 x 10³ cells/L

o Hemoglobin < 10 g/dL (<100 g/L)

o Creatinine Clearance (CrCl) ≤ 50 mL/min (as estimated by Cockcroft and Gault)

o Alpha fetoprotein (AFP):
  - AFP >100 ng/mL (> 82.6 IU/mL) OR
  - AFP ≥ 50 and ≤ 100 ng/mL (≥ 41.3 IU/mL and 82.6 IU/mL) requires a liver ultrasound and subjects with findings suspicious for HCC are excluded.

o QTcF or QTcB > 500 mSec
Allergies and Adverse Drug Reaction
  o History of hypersensitivity to drugs with a similar biochemical structure to DCV or SOF.
  o Any other criteria or known contraindication that would exclude the subject from receiving DCV or SOF per the local label.

Sex and Reproductive Status
  o Those males and females who do not or cannot meet the requirements outlined in Inclusion Criteria.
  o Sexually active fertile men whose partners are pregnant at screening are excluded from this study.

Prohibited Treatments and/or Therapies
  o Subjects (receiving cART regimens) who had first initiated anti-retroviral therapy within 6 months prior to Day 1 (Baseline) are excluded.

  o Use of prohibited cART regimens (See Supplementary Table S1) within one month of Day 1 (Baseline) and throughout the treatment period of the trial is prohibited. For subjects on prohibited cART regimens who are switched to permitted cART regimens at the discretion of their HIV care providers for the purpose of enrolling in the current study, subject must:
    ▪ Meet all of the above inclusion and exclusion criteria, and
    ▪ Be on the permitted cART for at least one month prior to Day 1 and
    ▪ Demonstrate complete HIV RNA suppression (HIV RNA < 50 copies/mL) at screening and prior to Day 1

Other Exclusion Criteria
  o Any other medical, psychiatric and/or social reason which, in the opinion of the investigator would make the subject inappropriate for the study

  o Prisoners or subjects who are involuntarily incarcerated

  o Subjects who are compulsorily detained for treatment of either a psychiatric or physical (e.g., infectious disease) illness
Figure S1. HCV RNA change from baseline on treatment with DCV + SOF
Figure S2. Sustained virologic responses and 95% confidence intervals for key subgroups by DCV + SOF treatment group (all treated patients)

Dashed vertical lines show overall SVR12 results and shaded regions show the associated overall confidence interval. Subgroups of N < 2 excluded

(A) Treatment-naive, 12 weeks
(B) Treatment-naïve, 8 weeks

- **HCV Genotype**
  - GT-1a: N = 36
  - GT-1b: N = 6
  - GT-2: N = 6
  - GT3: N = 3

- **Baseline Disease Characteristics**
  - HCV RNA < 6 x 10^4 IU/mL: N = 34
  - HCV RNA ≥ 6 x 10^4 IU/mL: N = 16
  - Cirrhotic: N = 5
  - Noncirrhotic: N = 44
  - IL28B-CC (RS1297980): N = 13
  - IL28B-nonCC (RS1297980): N = 37

- **Patient Demographics**
  - Male: N = 42
  - Female: N = 8
  - Age < 65 years: N = 47
  - Age ≥ 65 years: N = 3
  - White: N = 28
  - Black/African-American: N = 19
  - Other (excl. Asian): N = 2

- **cART Regimen**
  - Boosted PI-based: N = 29
  - Darunavir-ritonavir: N = 21
  - Nonnucleoside-based: N = 10
  - Other: N = 9

- **Baseline Immune Status**
  - 200–499 CD4 cells/mm^3: N = 21
  - ≥ 500 CD4 cells/mm^3: N = 28

Percent achieving SVR_{12}
(C) Treatment-experienced, 12 weeks

HCV Genotype
- GT-1a: N = 33
- GT-1b: N = 11
- GT-2: N = 2
- GT3: N = 4
- GT4: N = 2

Baseline Disease Characteristics
- HCV RNA <6 × 10^4 IU/mL: N = 33
- HCV RNA ≥6 × 10^4 IU/mL: N = 19
- Cirrhotic: N = 15
- Noncirrhotic: N = 54
- IL28B-CC (RS12979860): N = 13
- IL28B-nonCC (RS12979860): N = 36

Patient Demographics
- Male: N = 43
- Female: N = 9
- Age <55 years: N = 49
- Age ≥55 years: N = 3
- White: N = 31
- Black/African-American: N = 20

cART Regimen
- Boosted PI-based: N = 23
  - Darunavir-ritonavir: N = 11
- Nonnucleoside-based: N = 12
- Other: N = 16

Baseline Immune Status
- 200–499 CD4 cells/μL: N = 12
- ≥500 CD4 cells/μL: N = 39

Percent achieving SVR_{12}
(D) Combined 12-week treatment groups post hoc analysis

Combined 12-week treatment groups (treatment-naive and treatment-experienced). Vertical line and shaded region represent the overall SVR12 rate and 95% confidence interval, respectively, for all patients in the combined groups.
Figure S3. Baseline DCV resistance-associated polymorphisms in NS5A and associated sustained virologic response rates to DCV + SOF (all treatment groups)
Figure S4. CD4 cell counts on treatment with DCV + SOF

Patients on combination antiretroviral therapy (N = 199)
Table S1. List of permitted antiretrovirals

<table>
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<tr>
<th>Allowed antiretroviral agenta</th>
<th>Concomitant daclatasvir dose (once daily)</th>
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<tr>
<td><strong>Protease inhibitors (PIs)</strong></td>
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</tr>
<tr>
<td>Atazanavir + ritonavirb</td>
<td>30 mg</td>
</tr>
<tr>
<td>Darunavir + ritonavirb</td>
<td></td>
</tr>
<tr>
<td>Lopinavir + ritonavirb</td>
<td></td>
</tr>
<tr>
<td><strong>Nonnucleoside reverse transcriptase inhibitors (NNRTIs)</strong></td>
<td></td>
</tr>
<tr>
<td>Efavirenz</td>
<td>90 mg</td>
</tr>
<tr>
<td>Nevirapine</td>
<td></td>
</tr>
<tr>
<td>Rilpivirine</td>
<td>60 mg</td>
</tr>
<tr>
<td><strong>Integrase inhibitors</strong></td>
<td></td>
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<tr>
<td>Dolutegravir</td>
<td>60 mg</td>
</tr>
<tr>
<td>Raltegravir</td>
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<tr>
<td><strong>Entry inhibitors</strong></td>
<td></td>
</tr>
<tr>
<td>Enfuvirtide</td>
<td>60 mg</td>
</tr>
<tr>
<td>Maraviroc</td>
<td></td>
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<tr>
<td><strong>Nucleoside/nucleotide analogs</strong></td>
<td></td>
</tr>
<tr>
<td>Abacavir</td>
<td></td>
</tr>
<tr>
<td>Emtricitabine</td>
<td>60 mg</td>
</tr>
<tr>
<td>Lamivudine</td>
<td></td>
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<tr>
<td>Tenofovir disoproxil fumarate</td>
<td></td>
</tr>
<tr>
<td>Zidovudine</td>
<td></td>
</tr>
</tbody>
</table>

*a*Only medications listed in this column were permitted in the study. Changes to antiretroviral therapy were allowed at screening visit for subjects requiring a different regimen to meet study requirements. After regimen change, such subjects were required to remain on the new regimen for at least 1 month and have HIV RNA <50 copies/mL prior to study day 1.

*b*Pharmacokinetic booster doses of ritonavir only (subtherapeutic). All PIs **must** have been ritonavir-boosted. Unboosted PIs were disallowed. The use of alternative pharmacokinetic boosters (cobicistat) was disallowed.

The use of a protease inhibitor with any NNRTI other than rilpivirine was disallowed.
<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>Naive DCV/SOF 12 WK</th>
<th>Naive DCV/SOF 8 WK</th>
<th>Experienced DCV/SOF 12 WK</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>101</td>
<td>50</td>
<td>52</td>
<td>203</td>
</tr>
<tr>
<td>Mean</td>
<td>50.1</td>
<td>50.8</td>
<td>55.7</td>
<td>51.7</td>
</tr>
<tr>
<td>Median</td>
<td>52.0</td>
<td>50.5</td>
<td>56.5</td>
<td>52.0</td>
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<tr>
<td>Min, Max</td>
<td>24,71</td>
<td>28,75</td>
<td>43,66</td>
<td>24,75</td>
</tr>
<tr>
<td>Q1, Q3</td>
<td>46.0, 56.0</td>
<td>47.0, 56.0</td>
<td>51.0, 61.5</td>
<td>47.0, 58.0</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Age Categorization (%)</th>
<th>Naive DCV/SOF 12 WK</th>
<th>Naive DCV/SOF 8 WK</th>
<th>Experienced DCV/SOF 12 WK</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 65</td>
<td>96 (95.0)</td>
<td>47 (94.0)</td>
<td>49 (94.2)</td>
<td>192 (94.6)</td>
</tr>
<tr>
<td>≥ 65</td>
<td>5 (5.0)</td>
<td>3 (6.0)</td>
<td>3 (5.8)</td>
<td>11 (5.4)</td>
</tr>
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<table>
<thead>
<tr>
<th>Gender (%)</th>
<th>Naive DCV/SOF 12 WK</th>
<th>Naive DCV/SOF 8 WK</th>
<th>Experienced DCV/SOF 12 WK</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>92 (91.1)</td>
<td>42 (84.0)</td>
<td>43 (82.7)</td>
<td>177 (87.2)</td>
</tr>
<tr>
<td>Female</td>
<td>9 (8.9)</td>
<td>8 (16.0)</td>
<td>9 (17.3)</td>
<td>26 (12.8)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Race (%)</th>
<th>Naive DCV/SOF 12 WK</th>
<th>Naive DCV/SOF 8 WK</th>
<th>Experienced DCV/SOF 12 WK</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>White</td>
<td>66 (65.3)</td>
<td>28 (56.0)</td>
<td>31 (59.6)</td>
<td>125 (61.6)</td>
</tr>
<tr>
<td>Black/African American</td>
<td>30 (29.7)</td>
<td>19 (38.0)</td>
<td>20 (38.5)</td>
<td>69 (34.0)</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (1.0)</td>
<td>1 (2.0)</td>
<td>0</td>
<td>2 (1.0)</td>
</tr>
<tr>
<td>Asian Other</td>
<td>1 (1.0)</td>
<td>1 (2.0)</td>
<td>0</td>
<td>2 (1.0)</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>2 (2.0)</td>
<td>0</td>
<td>1 (1.9)</td>
<td>3 (1.5)</td>
</tr>
<tr>
<td>Native Hawaiian/Other Pacific Islander</td>
<td>0</td>
<td>2 (4.0)</td>
<td>0</td>
<td>2 (1.0)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (2.0)</td>
<td>0</td>
<td>0</td>
<td>2 (1.0)</td>
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<table>
<thead>
<tr>
<th>Ethnicity (%)</th>
<th>Naive DCV/SOF 12 WK</th>
<th>Naive DCV/SOF 8 WK</th>
<th>Experienced DCV/SOF 12 WK</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic/Latino</td>
<td>18 (17.8)</td>
<td>8 (16.0)</td>
<td>10 (19.2)</td>
<td>36 (17.7)</td>
</tr>
<tr>
<td>Not Hispanic/Latino</td>
<td>83 (82.2)</td>
<td>42 (84.0)</td>
<td>42 (80.8)</td>
<td>167 (82.3)</td>
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**Table S3. Baseline disease characteristics**

<table>
<thead>
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**Table S3. Baseline disease characteristics (cont.)**

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<td><strong>cART Regimen (%)</strong></td>
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Table S3. Baseline disease characteristics (cont.)

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Table S3. Baseline disease characteristics (cont.)

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<th>Naive DCV/SOF 8 WK N=50</th>
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Table S3. Baseline disease characteristics (cont.)

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<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
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<th>Naive DCV/SOF 8 WK N=50</th>
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<td>Mother-To-Child Transmission</td>
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<td>1 (2.0)</td>
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<td>7 (6.9)</td>
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<td>4 (7.7)</td>
<td>13 (6.4)</td>
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</tbody>
</table>

Fibrosis stage is derived from baseline fibrotest scores: F0: 0 - 0.27; F1: > 0.27 - 0.48; F2: > 0.48 - 0.58; F3: > 0.58 - 0.74; F4: > 0.74 - 1.00.

Cirrhosis was determined according to a testing hierarchy: (1) liver biopsy demonstrating cirrhosis any time before or during screening, then (2) fibroscan above 14.6 kPa within one year of baseline, then (3) a screening fibrotest fibrosis score of at least 0.75 with an APRI above 2.
Table S4. Details of Prior HCV treatments and outcomes

All patients received DCV + SOF for 12 weeks.

Includes one patient (genotype 1a, SVR12 responder with prior null response to peginterferon-ribavirin) randomized in error to the 12-week treatment-naïve group.

<table>
<thead>
<tr>
<th>#</th>
<th>Prior HCV Treatment</th>
<th>Prior Response</th>
<th>SVR12 (YES/NO)</th>
<th>HCV GT</th>
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<tbody>
<tr>
<td>1</td>
<td>IFN</td>
<td>INTOLERANCE</td>
<td>YES</td>
<td>1B</td>
</tr>
<tr>
<td>2</td>
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<td>NULL RESPONSE</td>
<td>YES</td>
<td>1A</td>
</tr>
<tr>
<td>3</td>
<td>PegIFN-RBV</td>
<td>INTOLERANCE</td>
<td>YES</td>
<td>1A</td>
</tr>
<tr>
<td>4</td>
<td>PegIFN-RBV</td>
<td>RELAPSE</td>
<td>YES</td>
<td>1B</td>
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<td>5</td>
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<td>6</td>
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<tr>
<td>7</td>
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<td>INTOLERANCE</td>
<td>YES</td>
<td>1B</td>
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<td>8</td>
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<td>9</td>
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<td>Outcome</td>
<td>Result</td>
<td>Genotype</td>
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<td>48</td>
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<td>49</td>
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<td>50</td>
<td>PegIFN-RBV + faldaprevir (BI201335)</td>
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<td>Sofosbuvir + RBV x 12 weeks</td>
<td>RELAPSE</td>
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<tr>
<td>52</td>
<td>Sofosbuvir + RBV x 24 weeks</td>
<td>RELAPSE</td>
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<td>1A</td>
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<td>53</td>
<td>Sofosbuvir + RBV x12 weeks</td>
<td>RELAPSE</td>
<td>YES</td>
<td>3</td>
</tr>
</tbody>
</table>

*GT, genotype; IFN, interferon alfa; PegIFN, pegylated interferon alfa; RBV, ribavirin*
Table S5. HCV RNA < 25 IU/mL (with or without target detected) by study visit

<table>
<thead>
<tr>
<th>Visit</th>
<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
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<tbody>
<tr>
<td>Week 1</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Responder/Evaluable (%)</td>
<td>35/101 (34.7)</td>
<td>22/50 (44.0)</td>
<td>18/52 (34.6)</td>
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<tr>
<td>95% CI</td>
<td>(25.5, 44.8)</td>
<td>(30.0, 58.7)</td>
<td>(22.0, 49.1)</td>
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<tr>
<td>Week 2</td>
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<td></td>
<td></td>
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<tr>
<td>Responder/Evaluable (%)</td>
<td>78/101 (77.2)</td>
<td>39/50 (78.0)</td>
<td>37/52 (71.2)</td>
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<tr>
<td>95% CI</td>
<td>(67.8, 85.0)</td>
<td>(64.0, 88.5)</td>
<td>(56.9, 82.9)</td>
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<tr>
<td>Week 4</td>
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<td></td>
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<tr>
<td>Responder/Evaluable (%)</td>
<td>94/101 (93.1)</td>
<td>49/50 (98.0)</td>
<td>48/52 (92.3)</td>
</tr>
<tr>
<td>95% CI</td>
<td>(86.2, 97.2)</td>
<td>(89.4, 99.9)</td>
<td>(81.5, 97.9)</td>
</tr>
<tr>
<td>Week 6</td>
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<td></td>
</tr>
<tr>
<td>Responder/Evaluable (%)</td>
<td>100/101 (99.0)</td>
<td>49/50 (98.0)</td>
<td>51/52 (98.1)</td>
</tr>
<tr>
<td>95% CI</td>
<td>(94.6, 100.0)</td>
<td>(89.4, 99.9)</td>
<td>(89.7, 100.0)</td>
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<tr>
<td>Week 8</td>
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<tr>
<td>Responder/Evaluable (%)</td>
<td>99/101 (98.0)</td>
<td>48/50 (96.0)</td>
<td>52/52 (100.0)</td>
</tr>
<tr>
<td>95% CI</td>
<td>(93.0, 99.8)</td>
<td>(86.3, 99.5)</td>
<td>(93.2, 100.0)</td>
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<tr>
<td>Week 12</td>
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<tr>
<td>Responder/Evaluable (%)</td>
<td>97/101 (96.0)</td>
<td>1/50 (2.0)</td>
<td>51/52 (98.1)</td>
</tr>
<tr>
<td>95% CI</td>
<td>(90.2, 98.9)</td>
<td>(0.1, 10.6)</td>
<td>(89.7, 100.0)</td>
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<td>End Of Treatment</td>
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<tr>
<td>Responder/Evaluable (%)</td>
<td>100/101 (99.0)</td>
<td>50/50 (100.0)</td>
<td>52/52 (100.0)</td>
</tr>
<tr>
<td>95% CI</td>
<td>(94.6, 100.0)</td>
<td>(92.9, 100.0)</td>
<td>(93.2, 100.0)</td>
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Table S5. HCV RNA < 25 IU/mL (with or without target detected) by study visit (cont.)

<table>
<thead>
<tr>
<th>Visit</th>
<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
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</thead>
<tbody>
<tr>
<td>F/U Week 4</td>
<td>Responders/Evaluable (%)</td>
<td>99/101 (98.0)</td>
<td>41/50 (82.0)</td>
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<td>95% CI</td>
<td>(93.0, 99.8)</td>
<td>(68.6, 91.4)</td>
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<tr>
<td>F/U Week 12*</td>
<td>Responders/Evaluable (%)</td>
<td>98/101 (97.0)</td>
<td>38/50 (76.0)</td>
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<td>95% CI</td>
<td>(91.6, 99.4)</td>
<td>(61.8, 86.9)</td>
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<tr>
<td>F/U Week 24†</td>
<td>Responders/Evaluable (%)</td>
<td>93/101 (92.1)</td>
<td>36/50 (72.0)</td>
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<td>95% CI</td>
<td>(85.0, 96.5)</td>
<td>(57.5, 83.8)</td>
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HCV RNA measurements are excluded after the start of non-study anti-HCV medication on-treatment or during follow-up.

*ITT, Next-Value-Carried-Backward †ITT, Missing=Failure
Table S6. SVR12 responses by subgroup

<table>
<thead>
<tr>
<th>Category</th>
<th>Subgroup</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 8 WK N=52</th>
<th>Combined (Naive + Experienced) DCV/SOF 12 WK N=153</th>
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</thead>
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<td>Naive DCV/SOF 12 WK N=101</td>
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<tr>
<td>Male</td>
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<td>92/92 (97.8)</td>
<td>42/43 (97.7)</td>
<td>132/135 (97.8)</td>
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<td></td>
<td>(92.4, 99.7)</td>
<td>(87.7, 99.9)</td>
<td>(93.6, 99.5)</td>
</tr>
<tr>
<td>Female</td>
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<td>33/42 (78.6)</td>
<td>9/9 (100.0)</td>
<td>17/18 (94.4)</td>
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<tr>
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<td>(63.2, 89.7)</td>
<td>(66.4, 100.0)</td>
<td>(72.7, 99.9)</td>
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<td>Age (Years)</td>
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<td>&lt; 65</td>
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<td>93/96 (96.9)</td>
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<td>(89.1, 99.9)</td>
<td>(93.1, 99.2)</td>
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<td>15/19 (78.9)</td>
<td>8/8 (100.0)</td>
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<td>(54.4, 93.9)</td>
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<td>(91.2, 99.4)</td>
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Table S6. SVR12 Responses By Subgroup (Cont.)

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<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
<th>Combined (Naive + Experienced) DCV/SOF 12 WK N=153</th>
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<td>Hispanic/Latino</td>
<td>Responders/Treated (%)</td>
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<td>28/28 (100.0)</td>
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<td>(69.2, 100.0)</td>
<td>(87.7, 100.0)</td>
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<td>Not Hispanic/Latino</td>
<td>Responders/Treated (%)</td>
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<td>(87.4, 99.9)</td>
<td>(92.0, 99.1)</td>
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### Table S6. SVR12 Responses By Subgroup (Cont.)

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Table S6. SVR12 Responses By Subgroup (Cont.)

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<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
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Table S6. SVR12 Responses By Subgroup (Cont.)

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<th>Experienced DCV/SOF 12 WK N=52</th>
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Table S6. SVR12 Responses By Subgroup (Cont.)

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Table S6. SVR12 Responses By Subgroup (Cont.)

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<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
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Table S6. SVR12 Responses By Subgroup (Cont.)

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Table S6. SVR12 Responses By Subgroup (Cont.)

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<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
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<td>21/29 (72.4)</td>
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<td>(90.1, 99.7)</td>
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| **Non-Nucleoside Reverse Transcriptase Inhibitor** | | | | |
| Overall | | | | |
| Responders/Treated (%) | 28/28 (100.0) | 8/10 (80.0) | 12/12 (100.0) | 40/40 (100.0) |
| 95% CI | (87.7, 100.0) | (44.4, 97.5) | (73.5, 100.0) | (91.2, 100.0) |
| **Efavirenz** | | | | |
| Responders/Treated (%) | 18/18 (100.0) | 7/8 (87.5) | 8/8 (100.0) | 26/26 (100.0) |
| 95% CI | (81.5, 100.0) | (47.3, 99.7) | (63.1, 100.0) | (86.8, 100.0) |
| **Nevirapine** | | | | |
| Responders/Treated (%) | 5/5 (100.0) | 1/1 (100.0) | 3/3 (100.0) | 8/8 (100.0) |
| 95% CI | (47.8, 100.0) | (2.5, 100.0) | (29.2, 100.0) | (63.1, 100.0) |
| **Rilpivirine** | | | | |
| Responders/Treated (%) | 5/5 (100.0) | 0/1 (0.0) | 1/1 (100.0) | 6/6 (100.0) |
| 95% CI | (47.8, 100.0) | (0.0, 97.5) | (2.5, 100.0) | (54.1, 100.0) |
Table S6. SVR12 Responses By Subgroup (Cont.)

<table>
<thead>
<tr>
<th>Category</th>
<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
<th>Combined (Naive + Experienced) DCV/SOF 12 WK N=153</th>
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**HCV Source**

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**Sexual Contact**

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**Other**

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| Responders/Treated (%) | 21/22 (95.5) | 4/8 (50.0) | 7/7 (100.0) | 28/29 (96.6) |
| 95% CI               | (77.2, 99.9) | (15.7, 84.3) | (59.0, 100.0) | (82.2, 99.9) |
Table S6. SVR12 Responses By Subgroup (Cont.)

<table>
<thead>
<tr>
<th>Category</th>
<th>Subgroup</th>
<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
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<td>Responders/Treated (%)</td>
<td></td>
<td>2/2 (100.0)</td>
<td>1/1 (100.0)</td>
<td>4/4 (100.0)</td>
<td>6/6 (100.0)</td>
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<tr>
<td>95% CI</td>
<td></td>
<td>(15.8, 100.0)</td>
<td>(2.5, 100.0)</td>
<td>(39.8, 100.0)</td>
<td>(54.1, 100.0)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Responders/Treated (%)</td>
<td></td>
<td>7/7 (100.0)</td>
<td>1/2 (50.0)</td>
<td>4/4 (100.0)</td>
<td>11/11 (100.0)</td>
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<tr>
<td>95% CI</td>
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<td>(59.0, 100.0)</td>
<td>(1.3, 98.7)</td>
<td>(39.8, 100.0)</td>
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HCV RNA Measurements Are Excluded After The Start Of Non-Study Anti-HCV Medication On-Treatment Or During Follow-Up. Svr12 Is Based On Next Value Carried Backwards Approach.
Table S7. Details of patients who did not achieve SVR12

<table>
<thead>
<tr>
<th>#</th>
<th>Age</th>
<th>Sex</th>
<th>Race</th>
<th>Tx arm</th>
<th>GT</th>
<th>cART base</th>
<th>DCV dose (mg)</th>
<th>Cirrhotic</th>
<th>BL HCV RNA (million IU/mL)</th>
<th>Reason for no SVR</th>
<th>NSSA RAPs at BL</th>
<th>NSSA RAPs at failure</th>
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<tbody>
<tr>
<td>1</td>
<td>56</td>
<td>M</td>
<td>Black</td>
<td>12-wk Exp</td>
<td>1a</td>
<td>CT</td>
<td>Darunavir 30</td>
<td>Yes</td>
<td>14.38</td>
<td>Relapse</td>
<td>None</td>
<td>Q30R</td>
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<tr>
<td>2</td>
<td>55</td>
<td>M</td>
<td>White</td>
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<td>CT</td>
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<td>10.28</td>
<td>Relapse</td>
<td>Y93Y/N</td>
<td>Y93SN</td>
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<td>3</td>
<td>34</td>
<td>M</td>
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<td>12-wk Naive</td>
<td>1a</td>
<td>CT</td>
<td>Raltegravir 60</td>
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<td>On-Tx failure</td>
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<td>Q30Q/R</td>
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<td>M</td>
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<td>1a</td>
<td>CC</td>
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<tr>
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<td>CT</td>
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<td>Relapse</td>
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<td>None</td>
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<td>42</td>
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<td>1a</td>
<td>CC</td>
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<td>10</td>
<td>50</td>
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<td>Black</td>
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<td>1a</td>
<td>TT</td>
<td>Efavirenz 90</td>
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<td>11</td>
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<td>8-wk Naive</td>
<td>1b</td>
<td>TT</td>
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<td>None</td>
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<td>Relapse</td>
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<td>L31M</td>
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<td>Relapse</td>
<td>A30A/S</td>
<td>A30S</td>
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<td>1a</td>
<td>CT</td>
<td>Raltegravir 60</td>
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<td>1.01</td>
<td>Lost to follow-up</td>
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<td>15</td>
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<td>M</td>
<td>White</td>
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<td>1b</td>
<td>CC</td>
<td>Rilpivirine 90</td>
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<td>TT</td>
<td>Raltegravir 60</td>
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<td>2.02</td>
<td>Lost to follow-up</td>
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</table>

*Noncompliant patient. Received 1.1 weeks of treatment and was <25 IU/mL with target detected at end-of-treatment measurement.

BL, baseline; cART, combination antiretroviral therapy; NA, not applicable; RAPs, daclatasvir resistance-associated polymorphisms at NSSA codons 28, 30, 31 or 93; Tx, treatment.
Table S8. Adverse events (grades 1-4) on treatment with DCV + SOF

<table>
<thead>
<tr>
<th>Preferred Term (%)</th>
<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
<th>Total N=203</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Subjects With An Event</strong></td>
<td>74 (73.3)</td>
<td>29 (58.0)</td>
<td>37 (71.2)</td>
<td>140 (69.0)</td>
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<tr>
<td><strong>Gastrointestinal Disorders</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>14 (13.9)</td>
<td>4 (8.0)</td>
<td>8 (15.4)</td>
<td>26 (12.8)</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>11 (10.9)</td>
<td>1 (2.0)</td>
<td>3 (5.8)</td>
<td>15 (7.4)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>6 (5.9)</td>
<td>1 (2.0)</td>
<td>3 (5.8)</td>
<td>10 (4.9)</td>
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<tr>
<td>Abdominal Pain</td>
<td>5 (5.0)</td>
<td>1 (2.0)</td>
<td>1 (1.9)</td>
<td>7 (3.4)</td>
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<tr>
<td>Constipation</td>
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<td>0</td>
<td>3 (5.8)</td>
<td>6 (3.0)</td>
</tr>
<tr>
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<td>1 (2.0)</td>
<td>1 (1.9)</td>
<td>3 (1.5)</td>
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<tr>
<td>Dry Mouth</td>
<td>1 (1.0)</td>
<td>0</td>
<td>2 (3.8)</td>
<td>3 (1.5)</td>
</tr>
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<td>0</td>
<td>2 (1.0)</td>
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<td>1 (1.9)</td>
<td>2 (1.0)</td>
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<td>0</td>
<td>1 (0.5)</td>
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<td>1 (0.5)</td>
</tr>
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<td>Abnormal Faeces</td>
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<td>1 (0.5)</td>
</tr>
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<td>1 (0.5)</td>
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<td>1 (0.5)</td>
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<td>1 (0.5)</td>
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<td>1 (0.5)</td>
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<td>0</td>
<td>1 (0.5)</td>
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Table S8. Adverse events (grades 1-4) on treatment with DCV + SOF (cont.)

<table>
<thead>
<tr>
<th>Preferred Term (%)</th>
<th>System Organ Class (%)</th>
<th>DCV/SOF 12 WK N=101</th>
<th>DCV/SOF 8 WK N=50</th>
<th>DCV/SOF 12 WK N=52</th>
<th>Total N=203</th>
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<td>Chest Pain</td>
<td>19 (18.8)</td>
<td>5 (10.0)</td>
<td>10 (19.2)</td>
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<td>0</td>
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<td>2 ( 1.0)</td>
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<tr>
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<td>1 ( 1.9)</td>
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Table S8. Adverse events (grades 1-4) on treatment with DCV + SOF (cont.)

<table>
<thead>
<tr>
<th>System Organ Class (%)</th>
<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
<th>Total N=203</th>
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<tr>
<td><strong>Preferred Term (%)</strong></td>
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<td></td>
<td></td>
<td></td>
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<tr>
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<td>1 (0.5)</td>
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Table S8. Adverse events (grades 1-4) on treatment with DCV + SOF (cont.)

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<th>System Organ Class (%)</th>
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<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
<th>Total N=203</th>
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Table S8. Adverse events (grades 1-4) on treatment with DCV + SOF (cont.)

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<th>System Organ Class (%)</th>
<th>Preferred Term (%)</th>
<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
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| Skin And Subcutaneous Tissue Disorders | | 11 (10.9) | 3 (6.0) | 5 (9.6) | 19 (9.4) |
|----------------------------------------|----------|----------|---------|----------|
| Rash                                   | 6 (5.9)  | 0        | 3 (5.8) | 9 (4.4)  |
| Pruritus                               | 2 (2.0)  | 1 (2.0)  | 1 (1.9) | 4 (2.0)  |
| Dermatitis Contact                     | 2 (2.0)  | 0        | 0       | 2 (1.0)  |
| Hyperhidrosis                          | 2 (2.0)  | 0        | 0       | 2 (1.0)  |
| Night Sweats                           | 0        | 1 (2.0)  | 1 (1.9) | 2 (1.0)  |
| Alopecia                               | 0        | 1 (2.0)  | 0       | 1 (0.5)  |
| Rash Papular                           | 0        | 0        | 1 (1.9) | 1 (0.5)  |

| Injury, Poisoning And Procedural Complications | | 3 (3.0) | 3 (6.0) | 3 (5.8) | 9 (4.4) |
|------------------------------------------------|----------|---------|---------|---------|
| Ligament Sprain                          | 1 (1.0)  | 2 (4.0) | 1 (1.9) | 4 (2.0) |
| Contusion                                | 0        | 0       | 1 (1.9) | 1 (0.5) |
| Fall                                     | 1 (1.0)  | 0       | 0       | 1 (0.5) |
| Foot Fracture                            | 0        | 0       | 1 (1.9) | 1 (0.5) |
| Foreign Body In Eye                      | 1 (1.0)  | 0       | 0       | 1 (0.5) |
| Laceration                               | 0        | 0       | 1 (1.9) | 1 (0.5) |
Table S8. Adverse events (grades 1-4) on treatment with DCV + SOF (cont.)

<table>
<thead>
<tr>
<th>System Organ Class (%)</th>
<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
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<td>Preferred Term (%)</td>
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Table S8. Adverse events (grades 1-4) on treatment with DCV + SOF (cont.)

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## Table S8. Adverse events (grades 1-4) on treatment with DCV + SOF (cont.)

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<th>System Organ Class (%)</th>
<th>Preferred Term (%)</th>
<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
<th>Total N=203</th>
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Table S9. Grade 3-4 adverse events on treatment with DCV + SOF

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<tr>
<th>n (%)</th>
<th>Treatment-naive 12 weeks N = 101</th>
<th>Treatment-naive 8 weeks N = 50</th>
<th>Treatment-experienced 12 weeks N = 52</th>
<th>Total N = 203</th>
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<tbody>
<tr>
<td>Patients with at least 1 event</td>
<td>2 (2.0)</td>
<td>2 (4.0)</td>
<td>4 (7.7)</td>
<td>8 (3.9)</td>
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<tr>
<td>Individual events (all grade 3)</td>
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<td></td>
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<tr>
<td>Decreased appetite</td>
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<tr>
<td>Pyrexia</td>
<td>1 (1.0)</td>
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<tr>
<td>Hypertension</td>
<td></td>
<td>1 (1.9)</td>
<td></td>
<td>1 (&lt;1)</td>
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<tr>
<td>Hypertensive crisis</td>
<td></td>
<td>1 (1.9)</td>
<td></td>
<td>1 (&lt;1)</td>
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<tr>
<td>Syncope</td>
<td></td>
<td>1 (1.9)</td>
<td></td>
<td>1 (&lt;1)</td>
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<td>Presyncope</td>
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<td>1 (1.9)</td>
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<td>1 (&lt;1)</td>
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<td>Priapism</td>
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<td></td>
<td>1 (&lt;1)</td>
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<td>Migraine</td>
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<td>1 (&lt;1)</td>
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<tr>
<td>Drug abuse</td>
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<td></td>
<td>1 (&lt;1)</td>
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<tr>
<td>Vomiting</td>
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<td>1 (&lt;1)</td>
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*Vertical bar identifies individual events occurring in a single patient*
Table S10. Serious Adverse Events

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<tr>
<th>Patient identifier</th>
<th>Study visit</th>
<th>Onset (study day)</th>
<th>Duration (days)</th>
<th>Preferred term</th>
<th>Treatment related?</th>
<th>Intensity</th>
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</thead>
<tbody>
<tr>
<td><strong>Treatment-naive 12-week treatment group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-102 (62/Male/Other)</td>
<td>Follow-up week 12</td>
<td>180</td>
<td>Continuing</td>
<td>Cholangiocarcinoma</td>
<td>Yes</td>
<td>Severe</td>
</tr>
<tr>
<td>8-40 (49/Male/Caucasian)</td>
<td>Week 4</td>
<td>23</td>
<td>3</td>
<td>Priapism</td>
<td>No</td>
<td>Severe</td>
</tr>
<tr>
<td>19-74 (46/Male/Black)</td>
<td>Follow-up week 4</td>
<td>99</td>
<td>17</td>
<td>Pneumonia</td>
<td>No</td>
<td>Moderate</td>
</tr>
<tr>
<td>28-187 (53/Male/Black)</td>
<td>Follow-up week 4</td>
<td>104</td>
<td>1</td>
<td>Osteoarthritis</td>
<td>No</td>
<td>Moderate</td>
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<tr>
<td>31-93 (55/Male/Caucasian)</td>
<td>Pre-treatment</td>
<td>-9</td>
<td>9</td>
<td>Post-procedural haematoma*</td>
<td>No</td>
<td>Very severe</td>
</tr>
<tr>
<td><strong>Treatment-naive 8-week treatment group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-90 (52/Male/Caucasian)</td>
<td>Follow-up week 4</td>
<td>96</td>
<td>1</td>
<td>Cardiac arrest</td>
<td>No</td>
<td>Very severe</td>
</tr>
<tr>
<td><strong>Treatment-experienced 12-week treatment group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-213 (52/Male/Caucasian)</td>
<td>Day 1</td>
<td>1</td>
<td>-</td>
<td>Chest pain</td>
<td>No</td>
<td>Moderate</td>
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<tr>
<td>7-67 (51/Male/Black)</td>
<td>Week 8</td>
<td>51</td>
<td>6</td>
<td>Drug abuse</td>
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<td>Severe</td>
</tr>
<tr>
<td></td>
<td>Week 12</td>
<td>80</td>
<td>15</td>
<td>Pulmonary embolism</td>
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<td>Severe</td>
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<tr>
<td>14-8 (60/Female/Black)</td>
<td>Week 8</td>
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<td>2</td>
<td>Hypertensive crisis</td>
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<td>Severe</td>
</tr>
<tr>
<td></td>
<td>Week 8</td>
<td>54</td>
<td>2</td>
<td>Syncope</td>
<td>No</td>
<td>Severe</td>
</tr>
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</table>

*Liver haematoma following biopsy
Table S11. Treatment-Emergent Laboratory Test Results By Worst Grade

<table>
<thead>
<tr>
<th>Lab Test Description</th>
<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
<th>Total N=203</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hemoglobin</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>50 (100.0)</td>
<td>52 (100.0)</td>
<td>203 (100.0)</td>
</tr>
<tr>
<td>Grade 1</td>
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<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Grade 2</td>
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<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Grade 3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Grade 4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Grades 1-4</td>
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<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Grades 3-4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

| **Platelet Count**    |                             |                          |                                |             |
| Not Emergent         | 94 (93.1)                   | 47 (94.0)                | 41 (80.4)                      | 182 (90.1)  |
| Grade 1              | 4 ( 4.0)                    | 2 ( 4.0)                | 9 (17.6)                      | 15 ( 7.4)   |
| Grade 2              | 3 ( 3.0)                    | 1 ( 2.0)                | 1 ( 2.0)                      | 5 ( 2.5)    |
| Grade 3              | 0                           | 0                        | 0                              | 0           |
| Grade 4              | 0                           | 0                        | 0                              | 0           |
| Grades 1-4           | 7 ( 6.9)                    | 3 ( 6.0)                | 10 (19.6)                     | 20 ( 9.9)   |
| Grades 3-4           | 0                           | 0                        | 0                              | 0           |

<p>| <strong>Intl Normalized Ratio (INR)</strong> |                             |                          |                                |             |
| Not Emergent         | 96 (95.0)                   | 49 (98.0)                | 47 (90.4)                      | 192 (94.6)  |
| Grade 1              | 4 ( 4.0)                    | 1 ( 2.0)                | 4 ( 7.7)                      | 9 ( 4.4)    |
| Grade 2              | 0                           | 0                        | 0                              | 0           |
| Grade 3              | 1 ( 1.0)                    | 0                        | 1 ( 1.9)                      | 2 ( 1.0)    |
| Grade 4              | 0                           | 0                        | 0                              | 0           |
| Grades 1-4           | 5 ( 5.0)                    | 1 ( 2.0)                | 5 ( 9.6)                      | 11 ( 5.4)   |
| Grades 3-4           | 1 ( 1.0)                    | 0                        | 1 ( 1.9)                      | 2 ( 1.0)    |</p>
<table>
<thead>
<tr>
<th>Lab Test Description</th>
<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
<th>Total N=203</th>
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<tbody>
<tr>
<td><strong>Leukocytes</strong></td>
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<tr>
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<td>N = 101 (99.0)</td>
<td>N = 50 (98.0)</td>
<td>N = 52 (96.2)</td>
<td>N = 203 (98.0)</td>
</tr>
<tr>
<td>Grade 1</td>
<td>1 (1.0)</td>
<td>1 (2.0)</td>
<td>2 (3.8)</td>
<td>4 (2.0)</td>
</tr>
<tr>
<td>Grade 2</td>
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<td>0</td>
<td>0</td>
</tr>
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<td>Grade 3</td>
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<td>Grade 4</td>
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<tr>
<td>Grades 1-4</td>
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<td>1 (2.0)</td>
<td>2 (3.8)</td>
<td>4 (2.0)</td>
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<td>Grades 3-4</td>
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<td>0</td>
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</tr>
<tr>
<td>Neutrophils + Bands (Absolute)</td>
<td>N = 101 (95.0)</td>
<td>N = 50 (92.0)</td>
<td>N = 52 (96.2)</td>
<td>N = 203 (94.6)</td>
</tr>
<tr>
<td>Not Emergent</td>
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<td>46 (92.0)</td>
<td>50 (96.2)</td>
<td>192 (94.6)</td>
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<td>7 (3.4)</td>
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<td>N = 52 (98.1)</td>
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<td>1 (1.9)</td>
<td>3 (1.5)</td>
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<tr>
<td>Grades 1-4</td>
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<td>3 (1.5)</td>
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<td>Grades 3-4</td>
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Table S11. Treatment-Emergent Laboratory Test Results By Worst Grade (cont.)

<table>
<thead>
<tr>
<th>Lab Test Description</th>
<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
<th>Total N=203</th>
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<tbody>
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<td>Aspartate Aminotransferase (AST)</td>
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<td>47 (94.0)</td>
<td>48 (92.3)</td>
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<td>3 ( 5.8)</td>
<td>8 ( 3.9)</td>
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<td>1 ( 1.9)</td>
<td>3 ( 1.5)</td>
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<td>1 ( 0.5)</td>
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<td>0</td>
</tr>
<tr>
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<td>4 ( 7.7)</td>
<td>12 ( 5.9)</td>
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<td>1 ( 0.5)</td>
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<td>50 (100.0)</td>
<td>52 (100.0)</td>
<td>203 (100.0)</td>
</tr>
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<td>Bilirubin, Total</td>
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<td>3 ( 1.5)</td>
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<td>7 ( 3.4)</td>
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<tr>
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<td>1 ( 1.0)</td>
<td>0</td>
<td>0</td>
<td>1 ( 0.5)</td>
</tr>
<tr>
<td>Grades 1-4</td>
<td>11 (10.9)</td>
<td>4 ( 8.0)</td>
<td>9 (17.3)</td>
<td>24 (11.8)</td>
</tr>
<tr>
<td>Grades 3-4</td>
<td>5 ( 5.0)</td>
<td>1 ( 2.0)</td>
<td>2 ( 3.8)</td>
<td>8 ( 3.9)</td>
</tr>
</tbody>
</table>
### Table S11. Treatment-Emergent Laboratory Test Results By Worst Grade (cont.)

<table>
<thead>
<tr>
<th>Lab Test Description</th>
<th>Toxicity Grade (%)</th>
<th>Naive DCV/SOF 12 WK N=101</th>
<th>Naive DCV/SOF 8 WK N=50</th>
<th>Experienced DCV/SOF 12 WK N=52</th>
<th>Total N=203</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Emergent</td>
<td>N = 101</td>
<td>101 (100.0)</td>
<td>52 (100.0)</td>
<td>201 (99.0)</td>
<td></td>
</tr>
<tr>
<td>Grade 1</td>
<td>0</td>
<td>1 ( 2.0)</td>
<td>0</td>
<td>1 ( 0.5)</td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td>0</td>
<td>1 ( 2.0)</td>
<td>0</td>
<td>1 ( 0.5)</td>
<td></td>
</tr>
<tr>
<td>Grade 3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Grade 4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Grades 1-4</td>
<td>0</td>
<td>2 ( 4.0)</td>
<td>0</td>
<td>2 ( 1.0)</td>
<td></td>
</tr>
<tr>
<td>Grades 3-4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Lipase, Total (Colorimetric Assay)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Emergent</td>
<td>N = 101</td>
<td>78 (77.2)</td>
<td>40 (76.9)</td>
<td>154 (75.9)</td>
<td></td>
</tr>
<tr>
<td>Grade 1</td>
<td>12 (11.9)</td>
<td>5 (10.0)</td>
<td>6 (11.5)</td>
<td>23 (11.3)</td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td>6 ( 5.9)</td>
<td>8 (16.0)</td>
<td>5 ( 9.6)</td>
<td>19 ( 9.4)</td>
<td></td>
</tr>
<tr>
<td>Grade 3</td>
<td>3 ( 3.0)</td>
<td>1 ( 2.0)</td>
<td>0</td>
<td>4 ( 2.0)</td>
<td></td>
</tr>
<tr>
<td>Grade 4</td>
<td>2 ( 2.0)</td>
<td>0</td>
<td>1 ( 1.9)</td>
<td>3 ( 1.5)</td>
<td></td>
</tr>
<tr>
<td>Grades 1-4</td>
<td>23 (22.8)</td>
<td>14 (28.0)</td>
<td>12 (23.1)</td>
<td>49 (24.1)</td>
<td></td>
</tr>
<tr>
<td>Grades 3-4</td>
<td>5 ( 5.0)</td>
<td>1 ( 2.0)</td>
<td>1 ( 1.9)</td>
<td>7 ( 3.4)</td>
<td></td>
</tr>
<tr>
<td>Creatinine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Emergent</td>
<td>N = 101</td>
<td>78 (77.2)</td>
<td>41 (78.8)</td>
<td>162 (79.8)</td>
<td></td>
</tr>
<tr>
<td>Grade 1</td>
<td>14 (13.9)</td>
<td>5 (10.0)</td>
<td>8 (15.4)</td>
<td>27 (13.3)</td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td>9 ( 8.9)</td>
<td>2 ( 4.0)</td>
<td>3 ( 5.8)</td>
<td>14 ( 6.9)</td>
<td></td>
</tr>
<tr>
<td>Grade 3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Grade 4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Grades 1-4</td>
<td>23 (22.8)</td>
<td>7 (14.0)</td>
<td>11 (21.2)</td>
<td>41 (20.2)</td>
<td></td>
</tr>
<tr>
<td>Grades 3-4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Toxicity Scale: DAIDS Version 1.0.

Treatment Emergent laboratory abnormalities are those with a higher toxicity grade on treatment than at baseline (including missing baseline).
Table S12. SVR24 details and SVR12/SVR24 concordance

<table>
<thead>
<tr>
<th></th>
<th>Treatment-naive DCV + SOF 12-weeks (N = 101)</th>
<th>Treatment-naive DCV + SOF 8-weeks (N = 50)</th>
<th>Treatment-experienced DCV + SOF 12-weeks (N = 52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVR12, % (n/N)</td>
<td>97.0 (98/101)</td>
<td>76.0 (38/50)</td>
<td>98.1 (51/52)</td>
</tr>
<tr>
<td>SVR24, % (n/N)</td>
<td>92.1 (93/101)</td>
<td>72.0 (36/50)</td>
<td>92.3 (48/52)</td>
</tr>
<tr>
<td>SVR24 non-responders, n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing posttreatment week 24 data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous SVR12 responder</td>
<td>4</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Previous SVR12 non-responder</td>
<td>1</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>With posttreatment week 24 data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous SVR12 non-responder</td>
<td>2</td>
<td>9</td>
<td>–</td>
</tr>
<tr>
<td>SVR12 response followed by relapse</td>
<td>–</td>
<td>1\textsuperscript{b}</td>
<td>–</td>
</tr>
<tr>
<td>SVR12 response followed by reinfection</td>
<td>1\textsuperscript{a}</td>
<td>–</td>
<td>1\textsuperscript{c}</td>
</tr>
<tr>
<td>SVR12/SVR24 result concordance, % (n/m)\textsuperscript{d}</td>
<td>99.0 (95/96)</td>
<td>97.8 (45/46)</td>
<td>98.0 (48/49)</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Available sequencing data suggest this subject (GT-2b at baseline) was reinfected with GT-3 following an SVR12 response.
\textsuperscript{b}Relapse of baseline virus confirmed by sequencing.
\textsuperscript{c}Available sequencing data suggest this subject (GT-1a at baseline) was reinfected with GT-1b following an SVR12 response.
\textsuperscript{d}Includes both SVR responder and SVR non-responder concordances; m = number of patients with data available at posttreatment weeks 12 and 24.
The Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events ("DAIDS AE Grading Table") is a descriptive terminology which can be utilized for Adverse Event (AE) reporting. A grading (severity) scale is provided for each AE term.

This clarification of the DAIDS Table for Grading the Severity of Adult and Pediatric AE’s provides additional explanation of the DAIDS AE Grading Table and clarifies some of the parameters.

I. Instructions and Clarifications

Grading Adult and Pediatric AEs

The DAIDS AE Grading Table includes parameters for grading both Adult and Pediatric AEs. When a single set of parameters is not appropriate for grading specific types of AEs for both Adult and Pediatric populations, separate sets of parameters for Adult and/or Pediatric populations (with specified respective age ranges) are given in the Table. If there is no distinction in the Table between Adult and Pediatric values for a type of AE, then the single set of parameters listed is to be used for grading the severity of both Adult and Pediatric events of that type.

Note: In the classification of adverse events, the term “severe” is not the same as “serious.” Severity is an indication of the intensity of a specific event (as in mild, moderate, or severe chest pain). The term “serious” relates to a participant/event outcome or action criteria, usually associated with events that pose a threat to a participant’s life or functioning.

Addenda 1-3 Grading Tables for Microbicide Studies

For protocols involving topical application of products to the female genital tract, male genital area or rectum, strong consideration should be given to using Appendices I-III as the primary grading scales for these areas. The protocol would need to specifically state that one or more of the Appendices would be primary (and thus take precedence over the main Grading Table) for items that are listed in both the Appendix and the main Grading Table.

Addendum 1 - Female Genital Grading Table for Use in Microbicide Studies - PDF
Addendum 2 - Male Genital Grading Table for Use in Microbicide Studies - PDF
Addendum 3 - Rectal Grading Table for Use in Microbicide Studies - PDF

Grade 5

For any AE where the outcome is death, the severity of the AE is classified as Grade 5.

Estimating Severity Grade for Parameters Not Identified in the Table

In order to grade a clinical AE that is not identified in the DAIDS AE grading table, use the category “Estimating Severity Grade” located on Page 3.

Determining Severity Grade for Parameters “Between Grades”

If the severity of a clinical AE could fall under either one of two grades (e.g., the severity of an AE could be either Grade 2 or Grade 3), select the higher of the two grades for the AE. If a laboratory value that is graded as a multiple of the ULN or LLN falls between two grades, select the higher of the two grades for the AE. For example, Grade 1 is 2.5 x ULN and Grade 2 is 2.6 x ULN for a parameter. If the lab value is 2.53 x ULN (which is between the two grades), the severity of this AE would be Grade 2, the higher of the two grades.

Values Below Grade 1

Any laboratory value that is between either the LLN or ULN and Grade 1 should not be graded.
In these situations, the severity grading is based on the ranges in the DAIDS AE Grading Table, even when there is a reference to the local lab LLN.

For example: Phosphate, Serum, Low, Adult and Pediatric > 14 years (Page 20) Grade 1 range is 2.50 mg/dL - < LLN. A particular laboratory’s normal range for Phosphate is 2.1 – 3.8 mg/dL. A participant’s actual lab value is 2.5. In this case, the value of 2.5 exceeds the LLN for the local lab, but will be graded as Grade 1 per DAIDS AE Grading Table.

II. Definitions of terms used in the Table:

<table>
<thead>
<tr>
<th>Basic Self-care Functions</th>
<th>Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Activities such as bathing, dressing, toileting, transfer/movement, continence, and feeding.</td>
</tr>
<tr>
<td></td>
<td>Young Children</td>
</tr>
<tr>
<td></td>
<td>Activities that are age and culturally appropriate (e.g., feeding self with culturally appropriate eating implement).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LLN</th>
<th>Lower limit of normal</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Medical Intervention</th>
<th>Use of pharmacologic or biologic agent(s) for treatment of an AE.</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Operative Intervention</th>
<th>Surgical OR other invasive mechanical procedures.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>ULN</th>
<th>Upper limit of normal</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Usual Social &amp; Functional Activities</th>
<th>Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adaptive tasks and desirable activities, such as going to work, shopping, cooking, use of transportation, pursuing a hobby, etc.</td>
</tr>
<tr>
<td></td>
<td>Young Children</td>
</tr>
<tr>
<td></td>
<td>Activities that are age and culturally appropriate (e.g., social interactions, play activities, learning tasks, etc.).</td>
</tr>
</tbody>
</table>
DIVISION OF AIDS TABLE FOR GRADING THE SEVERITY OF ADULT AND PEDIATRIC ADVERSE EVENTS
VERSION 1.0, DECEMBER, 2004; CLARIFICATION AUGUST 2009

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>GRADE 1</th>
<th>GRADE 2</th>
<th>GRADE 3</th>
<th>GRADE 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MILD</td>
<td>MODERATE</td>
<td>SEVERE</td>
<td>POTENTIALLY LIFE-THREATENING</td>
</tr>
</tbody>
</table>

**ESTIMATING SEVERITY GRADE**

<table>
<thead>
<tr>
<th>Clinical adverse event NOT identified elsewhere in this DAIDS AE Grading Table</th>
<th>Symptoms causing no or minimal interference with usual social &amp; functional activities</th>
<th>Symptoms causing greater than minimal interference with usual social &amp; functional activities</th>
<th>Symptoms causing inability to perform usual social &amp; functional activities</th>
<th>Symptoms causing inability to perform basic self-care functions OR Medical or operative intervention indicated to prevent permanent impairment, persistent disability, or death</th>
</tr>
</thead>
</table>

**SYSTEMIC**

<table>
<thead>
<tr>
<th>Acute systemic allergic reaction</th>
<th>Localized urticaria (wheals) with no medical intervention indicated</th>
<th>Localized urticaria with medical intervention indicated OR Mild angioedema with no medical intervention indicated</th>
<th>Generalized urticaria OR Angioedema with medical intervention indicated OR Symptomatic mild bronchospasm</th>
<th>Acute anaphylaxis OR Life-threatening bronchospasm OR Laryngeal edema</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Chills</th>
<th>Symptoms causing no or minimal interference with usual social &amp; functional activities</th>
<th>Symptoms causing greater than minimal interference with usual social &amp; functional activities</th>
<th>Symptoms causing inability to perform usual social &amp; functional activities</th>
<th>NA</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Fatigue Malaise</th>
<th>Symptoms causing no or minimal interference with usual social &amp; functional activities</th>
<th>Symptoms causing greater than minimal interference with usual social &amp; functional activities</th>
<th>Symptoms causing inability to perform usual social &amp; functional activities</th>
<th>Incapacitating fatigue/malaise symptoms causing inability to perform basic self-care functions</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Fever (nonaxillary)</th>
<th>37.7 – 38.6°C</th>
<th>38.7 – 39.3°C</th>
<th>39.4 – 40.5°C</th>
<th>&gt; 40.5°C</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Pain (indicate body site)</th>
<th>Pain causing no or minimal interference with usual social &amp; functional activities</th>
<th>Pain causing greater than minimal interference with usual social &amp; functional activities</th>
<th>Pain causing inability to perform usual social &amp; functional activities</th>
<th>Disabling pain causing inability to perform basic self-care functions OR Hospitalization (other than emergency room visit) indicated</th>
</tr>
</thead>
</table>

**Basic Self-care Functions – Adult**: Activities such as bathing, dressing, toileting, transfer/movement, continence, and feeding.

**Basic Self-care Functions – Young Children**: Activities that are age and culturally appropriate (e.g., feeding self with culturally appropriate eating implement).

**Usual Social & Functional Activities – Adult**: Adaptive tasks and desirable activities, such as going to work, shopping, cooking, use of transportation, pursuing a hobby, etc.

**Usual Social & Functional Activities – Young Children**: Activities that are age and culturally appropriate (e.g., social interactions, play activities, learning tasks, etc.).
DIVISION OF AIDS TABLE FOR GRADING THE SEVERITY OF ADULT AND PEDIATRIC ADVERSE EVENTS
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<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>GRADE 1 MILD</th>
<th>GRADE 2 MODERATE</th>
<th>GRADE 3 SEVERE</th>
<th>GRADE 4 POTENTIALLY LIFE-THREATENING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unintentional weight loss</td>
<td>NA</td>
<td>5 – 9% loss in body weight from baseline</td>
<td>10 – 19% loss in body weight from baseline</td>
<td>≥ 20% loss in body weight from baseline OR Aggressive intervention indicated [e.g., tube feeding or total parenteral nutrition (TPN)]</td>
</tr>
</tbody>
</table>

**INFECTION**

- **Infection (any other than HIV infection)**
  - Localized, no systemic antimicrobial treatment indicated AND Symptoms causing no or minimal interference with usual social & functional activities
  - Systemic antimicrobial treatment indicated OR Symptoms causing greater than minimal interference with usual social & functional activities
  - Systemic antimicrobial treatment indicated AND Symptoms causing inability to perform usual social & functional activities OR Operative intervention (other than simple incision and drainage) indicated
  - Life-threatening consequences (e.g., septic shock)

**INJECTION SITE REACTIONS**

- **Injection site pain (pain without touching)**
  - Pain/tenderness causing no or minimal limitation of use of limb
  - Pain/tenderness limiting use of limb OR Pain/tenderness causing greater than minimal interference with usual social & functional activities
  - Pain/tenderness causing inability to perform usual social & functional activities
  - Pain/tenderness causing inability to perform basic self-care function OR Hospitalization (other than emergency room visit) indicated for management of pain/tenderness

<table>
<thead>
<tr>
<th>Infection site reaction (localized)</th>
<th>Adult &gt; 15 years</th>
<th>Pediatric ≤ 15 years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Erythema OR Induration of 5x5 cm – 9x9 cm (or 25 cm² – 81 cm²)</strong></td>
<td>Erythema OR Induration OR Edema &gt; 9 cm any diameter (or &gt; 81 cm²)</td>
<td>Erythema OR Induration OR Edema &gt; 2.5 cm diameter but &lt; 50% surface area of the extremity segment (e.g., upper arm/thigh)</td>
</tr>
<tr>
<td><strong>Ulceration OR Secondary infection OR Phlebitis OR Sterile abscess OR Drainage</strong></td>
<td><strong>Necrosis (involving dermis and deeper tissue)</strong></td>
<td><strong>Necrosis (involving dermis and deeper tissue)</strong></td>
</tr>
</tbody>
</table>

**Basic Self-care Functions – Adult**: Activities such as bathing, dressing, toileting, transfer/movement, continence, and feeding.

**Basic Self-care Functions – Young Children**: Activities that are age and culturally appropriate (e.g., feeding self with culturally appropriate eating implement).

**Usual Social & Functional Activities – Adult**: Adaptive tasks and desirable activities, such as going to work, shopping, cooking, use of transportation, pursuing a hobby, etc.

**Usual Social & Functional Activities – Young Children**: Activities that are age and culturally appropriate (e.g., social interactions, play activities, learning tasks, etc.).
<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>GRADE 1</th>
<th>GRADE 2</th>
<th>GRADE 3</th>
<th>GRADE 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pruritis associated with injection See also Skin: Pruritis (itching - no skin lesions)</td>
<td>Itching localized to injection site AND Relieved spontaneously or with &lt; 48 hours treatment</td>
<td>Itching beyond the injection site but not generalized OR Itching localized to injection site requiring ≥ 48 hours treatment</td>
<td>Generalized itching causing inability to perform usual social &amp; functional activities</td>
<td>NA</td>
</tr>
<tr>
<td>SKIN – DERMATOLOGICAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alopecia</td>
<td>Thinning detectable by study participant (or by caregiver for young children and disabled adults)</td>
<td>Thinning or patchy hair loss detectable by health care provider</td>
<td>Complete hair loss</td>
<td>NA</td>
</tr>
<tr>
<td>Cutaneous reaction – rash</td>
<td>Localized macular rash</td>
<td>Diffuse macular, maculopapular, or morbilliform rash OR Target lesions</td>
<td>Diffuse macular, maculopapular, or morbilliform rash with vesicles or limited number of bullae OR Superficial ulcerations of mucous membrane limited to one site</td>
<td>Extensive or generalized bullous lesions OR Stevens-Johnson syndrome OR Ulceration of mucous membrane involving two or more distinct mucosal sites OR Toxic epidermal necrolysis (TEN)</td>
</tr>
<tr>
<td>Hyperpigmentation</td>
<td>Slight or localized</td>
<td>Marked or generalized</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Hypopigmentation</td>
<td>Slight or localized</td>
<td>Marked or generalized</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Pruritis (itching – no skin lesions) (See also Injection Site Reactions: Pruritis associated with injection)</td>
<td>Itching causing no or minimal interference with usual social &amp; functional activities</td>
<td>Itching causing greater than minimal interference with usual social &amp; functional activities</td>
<td>Itching causing inability to perform usual social &amp; functional activities</td>
<td>NA</td>
</tr>
<tr>
<td>CARDIOVASCULAR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac arrhythmia (general) (By ECG or physical exam)</td>
<td>Asymptomatic AND No intervention indicated</td>
<td>Asymptomatic AND Non-urgent medical intervention indicated</td>
<td>Symptomatic, non-life-threatening AND Non-urgent medical intervention indicated</td>
<td>Life-threatening arrhythmia OR Urgent intervention indicated</td>
</tr>
<tr>
<td>Cardiac-ischemia/infarction</td>
<td>NA</td>
<td>NA</td>
<td>Symptomatic ischemia (stable angina) OR Testing consistent with ischemia</td>
<td>Unstable angina OR Acute myocardial infarction</td>
</tr>
</tbody>
</table>

**Basic Self-care Functions – Adult:** Activities such as bathing, dressing, toileting, transfer/movement, continence, and feeding.

**Basic Self-care Functions – Young Children:** Activities that are age and culturally appropriate (e.g., feeding self with culturally appropriate eating implement).

**Usual Social & Functional Activities – Adult:** Adaptive tasks and desirable activities, such as going to work, shopping, cooking, use of transportation, pursuing a hobby, etc.

**Usual Social & Functional Activities – Young Children:** Activities that are age and culturally appropriate (e.g., social interactions, play activities, learning tasks, etc.).
### DIVISION OF AIDS TABLE FOR GRADING THE SEVERITY OF ADULT AND PEDIATRIC ADVERSE EVENTS
**VERSION 1.0, DECEMBER, 2004; CLARIFICATION AUGUST 2009**

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>GRADE 1 MILD</th>
<th>GRADE 2 MODERATE</th>
<th>GRADE 3 SEVERE</th>
<th>GRADE 4 POTENTIALLY LIFE-THREATENING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemorrhage (significant acute blood loss)</td>
<td>NA</td>
<td>Symptomatic AND No transfusion indicated</td>
<td>Symptomatic AND Transfusion of ≤ 2 units packed RBCs (for children ≤ 10 cc/kg) indicated</td>
<td>Life-threatening hypotension OR Transfusion of &gt; 2 units packed RBCs (for children &gt; 10 cc/kg) indicated</td>
</tr>
<tr>
<td><strong>Correction:</strong> in Grade 2 to 160 - 179 (systolic) and to ≥ 100 -109 (diastolic) and in Grade 3 to ≥ 180 from &gt; 180 (systolic) and to ≥ 110 from &gt; 110 (diastolic).</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Adult &gt; 17 years</strong> (with repeat testing at same visit)</td>
<td>140 – 159 mmHg systolic OR 90 – 99 mmHg diastolic</td>
<td>160 – 179 mmHg systolic OR 100 – 109 mmHg diastolic</td>
<td>≥ 180 mmHg systolic OR ≥ 110 mmHg diastolic</td>
<td>Life-threatening consequences (e.g., malignant hypertension) OR Hospitalization indicated (other than emergency room visit)</td>
</tr>
<tr>
<td><strong>Correction:</strong> in Grade 2 to 160 - 179 (systolic) and to ≥ 100 -109 (diastolic) and in Grade 3 to ≥ 180 from &gt; 180 (systolic) and to ≥ 110 from &gt; 110 (diastolic).</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pediatric ≤ 17 years</strong> (with repeat testing at same visit)</td>
<td>NA</td>
<td>91st – 94th percentile adjusted for age, height, and gender (systolic and/or diastolic)</td>
<td>≥ 95th percentile adjusted for age, height, and gender (systolic and/or diastolic)</td>
<td>Life-threatening consequences (e.g., malignant hypertension) OR Hospitalization indicated (other than emergency room visit)</td>
</tr>
<tr>
<td>Hypotension</td>
<td>NA</td>
<td>Symptomatic, corrected with oral fluid replacement</td>
<td>Symptomatic, IV fluids indicated</td>
<td>Shock requiring use of vaspressors or mechanical assistance to maintain blood pressure</td>
</tr>
<tr>
<td>Pericardial effusion</td>
<td>Asymptomatic, small effusion requiring no intervention</td>
<td>Asymptomatic, moderate or larger effusion requiring no intervention</td>
<td>Effusion with non-life threatening physiologic consequences OR Effusion with non-urgent intervention indicated</td>
<td>Life-threatening consequences (e.g., tamponade) OR Urgent intervention indicated</td>
</tr>
<tr>
<td>Prolonged PR interval</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Adult &gt; 16 years</strong></td>
<td>PR interval 0.21 – 0.25 sec</td>
<td>PR interval &gt; 0.25 sec</td>
<td>Type II 2nd degree AV block OR Ventricular pause &gt; 3.0 sec</td>
<td>Complete AV block</td>
</tr>
<tr>
<td><strong>Pediatric ≤ 16 years</strong></td>
<td>1st degree AV block (PR &gt; normal for age and rate)</td>
<td>Type I 2nd degree AV block</td>
<td>Type II 2nd degree AV block</td>
<td>Complete AV block</td>
</tr>
</tbody>
</table>

**Basic Self-care Functions – Adult:** Activities such as bathing, dressing, toileting, transfer/movement, continence, and feeding.

**Basic Self-care Functions – Young Children:** Activities that are age and culturally appropriate (e.g., feeding self with culturally appropriate eating implement).

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## DIVISION OF AIDS TABLE FOR GRADING THE SEVERITY OF ADULT AND PEDIATRIC ADVERSE EVENTS

**VERSION 1.0, DECEMBER, 2004; CLARIFICATION AUGUST 2009**

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>GRADE 1 MILD</th>
<th>GRADE 2 MODERATE</th>
<th>GRADE 3 SEVERE</th>
<th>GRADE 4 POTENTIALLY LIFE-THREATENING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolonged QTc</td>
<td>Asymptomatic, QTc interval 0.45 – 0.47 sec OR Increase interval &lt; 0.03 sec above baseline</td>
<td>Asymptomatic, QTc interval 0.48 – 0.49 sec OR Increase in interval 0.03 – 0.05 sec above baseline</td>
<td>Asymptomatic, QTc interval ≥ 0.50 sec OR Increase in interval ≥ 0.06 sec above baseline</td>
<td>Life-threatening consequences, e.g. Torsade de pointes or other associated serious ventricular dysrhythmia</td>
</tr>
<tr>
<td>Adult &gt; 16 years</td>
<td>Asymptomatic, QTc interval 0.450 – 0.464 sec</td>
<td>Asymptomatic, QTc interval 0.465 – 0.479 sec</td>
<td>Asymptomatic, QTc interval ≥ 0.480 sec</td>
<td>Life-threatening consequences, e.g. Torsade de pointes or other associated serious ventricular dysrhythmia</td>
</tr>
<tr>
<td>Pediatric ≤ 16 years</td>
<td>Asymptomatic, QTc interval 0.450 – 0.464 sec</td>
<td>Asymptomatic, QTc interval 0.465 – 0.479 sec</td>
<td>Asymptomatic, QTc interval ≥ 0.480 sec</td>
<td>Life-threatening consequences, e.g. Torsade de pointes or other associated serious ventricular dysrhythmia</td>
</tr>
<tr>
<td>Thrombosis/embolism</td>
<td>NA</td>
<td>Deep vein thrombosis AND No intervention indicated (e.g., anticoagulation, lysis filter, invasive procedure)</td>
<td>Deep vein thrombosis AND Intervention indicated (e.g., anticoagulation, lysis filter, invasive procedure)</td>
<td>Embolic event (e.g., pulmonary embolism, life-threatening thrombus)</td>
</tr>
<tr>
<td>Vasovagal episode (associated with a procedure of any kind)</td>
<td>Present without loss of consciousness</td>
<td>Present with transient loss of consciousness</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Ventricular dysfunction (congestive heart failure)</td>
<td>NA</td>
<td>Asymptomatic diagnostic finding AND intervention indicated</td>
<td>New onset with symptoms OR Worsening symptomatic congestive heart failure</td>
<td>Life-threatening congestive heart failure</td>
</tr>
<tr>
<td>GASTROINTESTINAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anorexia</td>
<td>Loss of appetite without decreased oral intake</td>
<td>Loss of appetite associated with decreased oral intake without significant weight loss</td>
<td>Loss of appetite associated with significant weight loss</td>
<td>Life-threatening consequences OR Aggressive intervention indicated [e.g., tube feeding or total parenteral nutrition (TPN)]</td>
</tr>
<tr>
<td>Ascites</td>
<td>Asymptomatic</td>
<td>Symptomatic AND Intervention indicated (e.g., diuretics or therapeutic paracentesis)</td>
<td>Symptomatic despite intervention</td>
<td>Life-threatening consequences</td>
</tr>
</tbody>
</table>

**Comment:** Please note that, while the grading scale provided for Unintentional Weight Loss may be used as a guideline when grading anorexia, this is not a requirement and should not be used as a substitute for clinical judgment.

---

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<th>GRADE 3</th>
<th>GRADE 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MILD</td>
<td>MODERATE</td>
<td>SEVERE</td>
<td>POTENTIALLY</td>
</tr>
<tr>
<td></td>
<td>NA</td>
<td>Symptomatic AND Medical intervention indicated</td>
<td>Radiologic, endoscopic, or operative intervention indicated</td>
<td>Life-threatening consequences (e.g., sepsis or perforation)</td>
</tr>
<tr>
<td></td>
<td>Constipation</td>
<td>Persistent constipation requiring regular use of dietary modifications, laxatives, or enemas</td>
<td>Obstipation with manual evacuation indicated</td>
<td>Life-threatening consequences (e.g., obstruction)</td>
</tr>
<tr>
<td>Cholecystitis</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Diarrhea

<table>
<thead>
<tr>
<th>Adult and Pediatric ≥ 1 year</th>
<th>Grade 1 (Transient or intermittent episodes of unformed stools OR Increase of ≤ 3 stools over baseline per 24-hour period)</th>
<th>Grade 2 (Persistent episodes of unformed to watery stools OR Increase of 4 – 6 stools over baseline per 24-hour period)</th>
<th>Grade 3 (Bloody diarrhea OR Increase of ≥ 7 stools per 24-hour period OR IV fluid replacement indicated)</th>
<th>Grade 4 (Life-threatening consequences (e.g., hypotensive shock))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric &lt; 1 year</td>
<td>Liquid stools (more unformed than usual) but usual number of stools</td>
<td>Liquid stools with increased number of stools OR Mild dehydration</td>
<td>Liquid stools with moderate dehydration</td>
<td>Liquid stools resulting in severe dehydration with aggressive rehydration indicated OR Hypotensive shock</td>
</tr>
</tbody>
</table>

### Dysphagia-Odynophagia

<table>
<thead>
<tr>
<th>Dysphagia-Odynophagia</th>
<th>Grade 1 (Symptomatic but able to eat usual diet)</th>
<th>Grade 2 (Symptoms causing altered dietary intake without medical intervention indicated)</th>
<th>Grade 3 (Symptoms causing severely altered dietary intake with medical intervention indicated)</th>
<th>Grade 4 (Life-threatening reduction in oral intake)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mucositis/stomatitis (clinical exam)</td>
<td>Indicate site (e.g., larynx, oral)</td>
<td>Erythema of the mucosa</td>
<td>Patchy pseudomembranes or ulcerations</td>
<td>Tissue necrosis OR Diffuse spontaneous mucosal bleeding OR Life-threatening consequences (e.g., aspiration, choking)</td>
</tr>
<tr>
<td>See Genitourinary for Vulvovaginitis</td>
<td>See also Dysphagia-Odynophagia and Proctitis</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Nausea

<table>
<thead>
<tr>
<th>Nausea</th>
<th>Grade 1 (Transient (&lt; 24 hours) or intermittent nausea with no or minimal interference with oral intake)</th>
<th>Grade 2 (Persistent nausea resulting in decreased oral intake for 24 – 48 hours)</th>
<th>Grade 3 (Persistent nausea resulting in minimal oral intake for &gt; 48 hours OR Aggressive rehydration indicated (e.g., IV fluids))</th>
<th>Grade 4 (Life-threatening consequences (e.g., hypotensive shock))</th>
</tr>
</thead>
</table>

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<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>GRADE 1 MILD</th>
<th>GRADE 2 MODERATE</th>
<th>GRADE 3 SEVERE</th>
<th>GRADE 4 POTENTIALLY LIFE-THREATENING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatitis</td>
<td>NA</td>
<td>Symptomatic AND Hospitalization not indicated (other than emergency room visit)</td>
<td>Symptomatic AND Hospitalization indicated (other than emergency room visit)</td>
<td>Life-threatening consequences (e.g., circulatory failure, hemorrhage, sepsis)</td>
</tr>
<tr>
<td>Proctitis (functional-symptomatic)</td>
<td>Rectal discomfort AND No intervention indicated</td>
<td>Symptoms causing greater than minimal interference with usual social &amp; functional activities OR Medical intervention indicated</td>
<td>Symptoms causing inability to perform usual social &amp; functional activities OR Operative intervention indicated</td>
<td>Life-threatening consequences (e.g., perforation)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>Transient or intermittent vomiting with no or minimal interference with oral intake</td>
<td>Frequent episodes of vomiting with no or mild dehydration</td>
<td>Persistent vomiting resulting in orthostatic hypotension OR Aggressive rehydration indicated (e.g., IV fluids)</td>
<td>Life-threatening consequences (e.g., hypotensive shock)</td>
</tr>
<tr>
<td>NEUROLOGIC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alteration in personality-behavior or in mood (e.g., agitation, anxiety, depression, mania, psychosis)</td>
<td>Alteration causing no or minimal interference with usual social &amp; functional activities</td>
<td>Alteration causing greater than minimal interference with usual social &amp; functional activities</td>
<td>Alteration causing inability to perform usual social &amp; functional activities</td>
<td>Behavior potentially harmful to self or others (e.g., suicidal and homicidal ideation or attempt, acute psychosis) OR Causing inability to perform basic self-care functions</td>
</tr>
<tr>
<td>Altered Mental Status For Dementia, see Cognitive and behavioral/attentional disturbance (including dementia and attention deficit disorder)</td>
<td>Changes causing no or minimal interference with usual social &amp; functional activities</td>
<td>Mild lethargy or somnolence causing greater than minimal interference with usual social &amp; functional activities</td>
<td>Confusion, memory impairment, lethargy, or somnolence causing inability to perform usual social &amp; functional activities</td>
<td>Delirium OR obtundation, OR coma</td>
</tr>
<tr>
<td>Ataxia</td>
<td>Asymptomatic ataxia detectable on exam OR Minimal ataxia causing no or minimal interference with usual social &amp; functional activities</td>
<td>Symptomatic ataxia causing greater than minimal interference with usual social &amp; functional activities</td>
<td>Symptomatic ataxia causing inability to perform usual social &amp; functional activities</td>
<td>Disabling ataxia causing inability to perform basic self-care functions</td>
</tr>
</tbody>
</table>

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**VERSION 1.0, DECEMBER, 2004; CLARIFICATION AUGUST 2009**

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>GRADE 1 MILD</th>
<th>GRADE 2 MODERATE</th>
<th>GRADE 3 SEVERE</th>
<th>GRADE 4 POTENTIALLY LIFE-THREATENING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive and behavioral/attentional disturbance (including dementia and attention deficit disorder)</td>
<td>Disability causing no or minimal interference with usual social &amp; functional activities OR Specialized resources not indicated</td>
<td>Disability causing greater than minimal interference with usual social &amp; functional activities OR Specialized resources on part-time basis indicated</td>
<td>Disability causing inability to perform usual social &amp; functional activities OR Specialized resources on a full-time basis indicated</td>
<td>Disability causing inability to perform basic self-care functions OR Institutionalization indicated</td>
</tr>
<tr>
<td>CNS ischemia (acute)</td>
<td>NA</td>
<td>NA</td>
<td>Transient ischemic attack</td>
<td>Cerebral vascular accident (CVA, stroke) with neurological deficit</td>
</tr>
<tr>
<td>Developmental delay – Pediatric ≤ 16 years</td>
<td>Mild developmental delay, either motor or cognitive, as determined by comparison with a developmental screening tool appropriate for the setting</td>
<td>Moderate developmental delay, either motor or cognitive, as determined by comparison with a developmental screening tool appropriate for the setting</td>
<td>Severe developmental delay, either motor or cognitive, as determined by comparison with a developmental screening tool appropriate for the setting</td>
<td>Developmental regression, either motor or cognitive, as determined by comparison with a developmental screening tool appropriate for the setting</td>
</tr>
<tr>
<td>Headache</td>
<td>Symptoms causing no or minimal interference with usual social &amp; functional activities</td>
<td>Symptoms causing greater than minimal interference with usual social &amp; functional activities</td>
<td>Symptoms causing inability to perform usual social &amp; functional activities</td>
<td>Symptoms causing inability to perform basic self-care functions OR Hospitalization indicated (other than emergency room visit) OR Headache with significant impairment of alertness or other neurologic function</td>
</tr>
<tr>
<td>Insomnia</td>
<td>NA</td>
<td>Difficulty sleeping causing greater than minimal interference with usual social &amp; functional activities</td>
<td>Difficulty sleeping causing inability to perform usual social &amp; functional activities</td>
<td>Disabling insomnia causing inability to perform basic self-care functions</td>
</tr>
<tr>
<td>Neuromuscular weakness (including myopathy &amp; neuropathy)</td>
<td>Asymptomatic with decreased strength on exam OR Minimal muscle weakness causing no or minimal interference with usual social &amp; functional activities</td>
<td>Muscle weakness causing greater than minimal interference with usual social &amp; functional activities</td>
<td>Muscle weakness causing inability to perform usual social &amp; functional activities</td>
<td>Disabling muscle weakness causing inability to perform basic self-care functions OR Respiratory muscle weakness impairing ventilation</td>
</tr>
</tbody>
</table>

---

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<tr>
<th>PARAMETER</th>
<th>GRADE 1</th>
<th>GRADE 2</th>
<th>GRADE 3</th>
<th>GRADE 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MILD</td>
<td>MODERATE</td>
<td>SEVERE</td>
<td>POTENTIALLY LIFE-THREATENING</td>
</tr>
<tr>
<td>Neurosensory alteration (including paresthesia and painful neuropathy)</td>
<td>Asymptomatic with sensory alteration on exam or minimal paresthesia causing no or minimal interference with usual social &amp; functional activities</td>
<td>Sensory alteration or paresthesia causing greater than minimal interference with usual social &amp; functional activities</td>
<td>Sensory alteration or paresthesia causing inability to perform usual social &amp; functional activities</td>
<td>Disabling sensory alteration or paresthesia causing inability to perform basic self-care functions</td>
</tr>
<tr>
<td>Seizure: (new onset) – Adult ≥ 18 years</td>
<td>NA</td>
<td>1 seizure</td>
<td>2 – 4 seizures</td>
<td>Seizures of any kind which are prolonged, repetitive (e.g., status epilepticus), or difficult to control (e.g., refractory epilepsy)</td>
</tr>
<tr>
<td>See also Seizure: (known pre-existing seizure disorder)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seizure: (known pre-existing seizure disorder) – Adult ≥ 18 years</td>
<td>NA</td>
<td>Increased frequency of pre-existing seizures (non-repetitive) without change in seizure character OR Infrequent breakthrough seizures while on stable medication in a previously controlled seizure disorder</td>
<td>Change in seizure character from baseline either in duration or quality (e.g., severity or focality)</td>
<td>Seizures of any kind which are prolonged, repetitive (e.g., status epilepticus), or difficult to control (e.g., refractory epilepsy)</td>
</tr>
<tr>
<td>For worsening of existing epilepsy the grades should be based on an increase from previous level of control to any of these levels.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seizure – Pediatric &lt; 18 years</td>
<td>Seizure, generalized onset with or without secondary generalization, lasting &lt; 5 minutes with &lt; 24 hours post ictal state</td>
<td>Seizure, generalized onset with or without secondary generalization, lasting 5 – 20 minutes with &lt; 24 hours post ictal state</td>
<td>Seizure, generalized onset with or without secondary generalization, lasting &gt; 20 minutes</td>
<td>Seizure, generalized onset with or without secondary generalization, requiring intubation and sedation</td>
</tr>
<tr>
<td>Syncope (not associated with a procedure)</td>
<td>NA</td>
<td>Present</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Vertigo</td>
<td>Vertigo causing no or minimal interference with usual social &amp; functional activities</td>
<td>Vertigo causing greater than minimal interference with usual social &amp; functional activities</td>
<td>Vertigo causing inability to perform usual social &amp; functional activities</td>
<td>Disabling vertigo causing inability to perform basic self-care functions</td>
</tr>
</tbody>
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**VERSION 1.0, DECEMBER, 2004; CLARIFICATION AUGUST 2009**

| PARAMETER | GRADE 1  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MILD</td>
</tr>
<tr>
<td><strong>RESPIRATORY</strong></td>
<td></td>
</tr>
<tr>
<td>Bronchospasm (acute)</td>
<td>FEV1 or peak flow reduced to 70 – 80%</td>
</tr>
<tr>
<td>Dyspnea or respiratory distress</td>
<td></td>
</tr>
<tr>
<td>Adult ≥ 14 years</td>
<td>Dyspnea on exertion with no or minimal interference with usual social &amp; functional activities</td>
</tr>
<tr>
<td>Pediatric &lt; 14 years</td>
<td>Wheezing OR minimal increase in respiratory rate for age</td>
</tr>
<tr>
<td><strong>MUSCULOSKELETAL</strong></td>
<td></td>
</tr>
<tr>
<td>Arthralgia</td>
<td>Joint pain causing no or minimal interference with usual social &amp; functional activities</td>
</tr>
<tr>
<td>Arthritis</td>
<td>Stiffness or joint swelling causing no or minimal interference with usual social &amp; functional activities</td>
</tr>
<tr>
<td>Bone Mineral Loss</td>
<td></td>
</tr>
<tr>
<td>Adult ≥ 21 years</td>
<td>BMD t-score -2.5 to -1.0</td>
</tr>
<tr>
<td>Pediatric &lt; 21 years</td>
<td>BMD z-score -2.5 to -1.0</td>
</tr>
<tr>
<td>Myalgia (non-injection site)</td>
<td>Muscle pain causing no or minimal interference with usual social &amp; functional activities</td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Osteonecrosis</td>
<td>NA</td>
<td>Asymptomatic with radiographic findings AND No operative intervention indicated</td>
<td>Symptomatic bone pain with radiographic findings OR Operative intervention indicated</td>
<td>Disabling bone pain with radiographic findings causing inability to perform basic self-care functions</td>
</tr>
</tbody>
</table>

**GENITOURINARY**

<table>
<thead>
<tr>
<th>Cervicitis (symptoms)</th>
<th>Symptoms causing no or minimal interference with usual social &amp; functional activities</th>
<th>Symptoms causing greater than minimal interference with usual social &amp; functional activities</th>
<th>Symptoms causing inability to perform usual social &amp; functional activities</th>
<th>Symptoms causing inability to perform basic self-care functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>(For use in studies evaluating topical study agents)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For other cervicitis see Infection: Infection (any other than HIV infection)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cervicitis (clinical exam)</td>
<td>Minimal cervical abnormalities on examination (erythema, mucopurulent discharge, or friability) OR Epithelial disruption &lt; 25% of total surface</td>
<td>Moderate cervical abnormalities on examination (erythema, mucopurulent discharge, or friability) OR Epithelial disruption of 25 – 49% total surface</td>
<td>Severe cervical abnormalities on examination (erythema, mucopurulent discharge, or friability) OR Epithelial disruption of 50 – 75% total surface</td>
<td>Epithelial disruption &gt; 75% total surface</td>
</tr>
<tr>
<td>(For use in studies evaluating topical study agents)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For other cervicitis see Infection: Infection (any other than HIV infection)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inter-menstrual bleeding (IMB)</td>
<td>Spotting observed by participant OR Minimal blood observed during clinical or colposcopic examination</td>
<td>Inter-menstrual bleeding not greater in duration or amount than usual menstrual cycle</td>
<td>Inter-menstrual bleeding greater in duration or amount than usual menstrual cycle</td>
<td>Hemorrhage with life-threatening hypotension OR Operative intervention indicated</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary tract obstruction (e.g., stone)</td>
<td>NA</td>
<td>Signs or symptoms of urinary tract obstruction without hydronephrosis or renal dysfunction</td>
<td>Signs or symptoms of urinary tract obstruction with hydronephrosis or renal dysfunction</td>
<td>Obstruction causing life-threatening consequences</td>
</tr>
</tbody>
</table>

**Basic Self-care Functions – Adult:** Activities such as bathing, dressing, toileting, transfer/movement, continence, and feeding.

**Basic Self-care Functions – Young Children:** Activities that are age and culturally appropriate (e.g., feeding self with culturally appropriate eating implement).

**Usual Social & Functional Activities – Adult:** Adaptive tasks and desirable activities, such as going to work, shopping, cooking, use of transportation, pursuing a hobby, etc.

**Usual Social & Functional Activities – Young Children:** Activities that are age and culturally appropriate (e.g., social interactions, play activities, learning tasks, etc.).
### DIVISION OF AIDS TABLE FOR GRADING THE SEVERITY OF ADULT AND PEDIATRIC ADVERSE EVENTS
**VERSION 1.0, DECEMBER, 2004; CLARIFICATION AUGUST 2009**

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>GRADE 1</th>
<th>GRADE 2</th>
<th>GRADE 3</th>
<th>GRADE 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vulvovaginitis (symptoms)</td>
<td>Symptoms causing no or minimal interference with usual social &amp; functional activities</td>
<td>Symptoms causing greater than minimal interference with usual social &amp; functional activities</td>
<td>Symptoms causing inability to perform usual social &amp; functional activities</td>
<td>Symptoms causing inability to perform basic self-care functions</td>
</tr>
<tr>
<td>Vulvovaginitis (clinical exam)</td>
<td>Minimal vaginal abnormalities on examination OR Epithelial disruption &lt; 25% of total surface</td>
<td>Moderate vaginal abnormalities on examination OR Epithelial disruption of 25 - 49% total surface</td>
<td>Severe vaginal abnormalities on examination OR Epithelial disruption 50 - 75% total surface</td>
<td>Vaginal perforation OR Epithelial disruption &gt; 75% total surface</td>
</tr>
</tbody>
</table>

### OCULAR/VISUAL

<table>
<thead>
<tr>
<th>Uveitis</th>
<th>Visual changes (from baseline)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic but detectable on exam</td>
<td>Visual changes causing no or minimal interference with usual social &amp; functional activities</td>
</tr>
<tr>
<td>Symptomatic anterior uveitis OR Medical intervention indicated</td>
<td>Visual changes causing greater than minimal interference with usual social &amp; functional activities</td>
</tr>
<tr>
<td>Posterior or pan-uveitis OR Operative intervention indicated</td>
<td>Visual changes causing inability to perform usual social &amp; functional activities</td>
</tr>
<tr>
<td>Disabling visual loss in affected eye(s)</td>
<td>Disabling visual loss in affected eye(s)</td>
</tr>
</tbody>
</table>

### ENDOCRINE/METABOLIC

| Abnormal fat accumulation (e.g., back of neck, breasts, abdomen) | Diabetes mellitus |
| Detectable by study participant (or by caregiver for young children and disabled adults) | NA |
| Detectable on physical exam by health care provider | New onset without need to initiate medication OR Modification of current medications to regain glucose control |
| Disfiguring OR Obvious changes on casual visual inspection | New onset with initiation of medication indicated OR Diabetes uncontrolled despite treatment modification |
| Life-threatening consequences (e.g., ketoacidosis, hyperosmolar non-ketotic coma) |

**Basic Self-care Functions – Adult**: Activities such as bathing, dressing, toileting, transfer/movement, continence, and feeding.

**Basic Self-care Functions – Young Children**: Activities that are age and culturally appropriate (e.g., feeding self with culturally appropriate eating implement).

**Usual Social & Functional Activities – Adult**: Adaptive tasks and desirable activities, such as going to work, shopping, cooking, use of transportation, pursuing a hobby, etc.

**Usual Social & Functional Activities – Young Children**: Activities that are age and culturally appropriate (e.g., social interactions, play activities, learning tasks, etc.).
<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>GRADE 1 MILD</th>
<th>GRADE 2 MODERATE</th>
<th>GRADE 3 SEVERE</th>
<th>GRADE 4 POTENTIALLY LIFE-THRATENING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gynecomastia</td>
<td>Detectable by study participant or caregiver (for young children and disabled adults)</td>
<td>Detectable on physical exam by health care provider</td>
<td>Disfiguring OR Obvious on casual visual inspection</td>
<td>NA</td>
</tr>
<tr>
<td>Hyperthyroidism</td>
<td>Asymptomatic</td>
<td>Symptomatic causing greater than minimal interference with usual social &amp; functional activities OR Thyroid suppression therapy indicated</td>
<td>Symptoms causing inability to perform usual social &amp; functional activities OR Uncontrolled despite treatment modification</td>
<td>Life-threatening consequences (e.g., thyroid storm)</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>Asymptomatic</td>
<td>Symptomatic causing greater than minimal interference with usual social &amp; functional activities OR Thyroid replacement therapy indicated</td>
<td>Symptoms causing inability to perform usual social &amp; functional activities OR Uncontrolled despite treatment modification</td>
<td>Life-threatening consequences (e.g., myxedema coma)</td>
</tr>
<tr>
<td>Lipoatrophy (e.g., fat loss from the face, extremities, buttocks)</td>
<td>Detectable by study participant (or by caregiver for young children and disabled adults)</td>
<td>Detectable on physical exam by health care provider</td>
<td>Disfiguring OR Obvious on casual visual inspection</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Basic Self-care Functions – Adult:** Activities such as bathing, dressing, toileting, transfer/movement, continence, and feeding.

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<tr>
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<th>GRADE 3 SEVERE</th>
<th>GRADE 4 POTENTIALLY LIFE-THREATENING</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEMATOLOGY</td>
<td>Standard International Units are listed in italics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absolute CD4+ count – Adult and Pediatric &gt; 13 years (HIV NEGATIVE ONLY)</td>
<td>300 – 400/mm³</td>
<td>200 – 299/mm³</td>
<td>100 – 199/mm³</td>
<td>&lt; 100/mm³</td>
</tr>
<tr>
<td></td>
<td>300 – 400/µL</td>
<td>200 – 299/µL</td>
<td>100 – 199/µL</td>
<td>&lt; 100/µL</td>
</tr>
<tr>
<td>Absolute lymphocyte count – Adult and Pediatric &gt; 13 years (HIV NEGATIVE ONLY)</td>
<td>600 – 650/mm³</td>
<td>500 – 599/mm³</td>
<td>350 – 499/mm³</td>
<td>&lt; 350/mm³</td>
</tr>
<tr>
<td></td>
<td>0.600 x 10⁹ – 0.650 x 10⁹/L</td>
<td>0.500 x 10⁹ – 0.599 x 10⁹/L</td>
<td>0.350 x 10⁹ – 0.499 x 10⁹/L</td>
<td>&lt; 0.350 x 10⁹/L</td>
</tr>
</tbody>
</table>

**Comment:** Values in children ≤ 13 years are not given for the two parameters above because the absolute counts are variable.

Absolute neutrophil count (ANC)

| Adult and Pediatric, > 7 days | 1,000 – 1,300/mm³ | 750 – 999/mm³ | 500 – 749/mm³ | < 500/mm³ |
| | 1,000 x 10⁹ – 1.300 x 10⁹/L | 750 – 999 x 10⁹/L | 500 – 749 x 10⁹/L | < 0.500 x 10⁹/L |
| Infant*, 2 – ≤ 7 days | 1,250 – 1,500/mm³ | 1,000 – 1,249/mm³ | 750 – 999/mm³ | < 750/mm³ |
| | 1.250 x 10⁹ – 1.500 x 10⁹/L | 1.000 x 10⁹ – 1.249 x 10⁹/L | 750 – 999 x 10⁹/L | < 0.750 x 10⁹/L |
| Infant†, ≤ 1 day | 4,000 – 5,000/mm³ | 3,000 – 3,999/mm³ | 1,500 – 2,999/mm³ | < 1,500/mm³ |
| | 4.000 x 10⁹ – 5.000 x 10⁹/L | 3.000 x 10⁹ – 3.999 x 10⁹/L | 1.500 x 10⁹ – 2.999 x 10⁹/L | < 1.500 x 10⁹/L |

**Comment:** Parameter changed from “Infant, < 1 day” to “Infant, ≤ 1 day”

Fibrinogen, decreased

| 100 – 200 mg/dL | 75 – 99 mg/dL | 50 – 74 mg/dL | < 50 mg/dL |
| 1.00 – 2.00 g/L | 0.75 – 0.99 g/L | 0.50 – 0.74 g/L | < 0.50 g/L |
| 0.75 – 0.99 x LLN | 0.50 – 0.74 x LLN | 0.25 – 0.49 x LLN | OR |

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<tr>
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<th>GRADE 1</th>
<th>GRADE 2</th>
<th>GRADE 3</th>
<th>GRADE 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MILD</td>
<td>MODERATE</td>
<td>SEVERE</td>
<td>LIFE-THREATENING</td>
</tr>
<tr>
<td>Hemoglobin (Hgb)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Comment:</strong> The Hgb values in mmol/L have changed because the conversion factor used to convert g/dL to mmol/L has been changed from 0.155 to 0.6206 (the most commonly used conversion factor). For grading Hgb results obtained by an analytic method with a conversion factor other than 0.6206, the result must be converted to g/dL using the appropriate conversion factor for that lab.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult and Pediatric ≥ 57 days</td>
<td>8.5 – 10.0 g/dL</td>
<td>7.5 – 8.4 g/dL</td>
<td>6.50 – 7.4 g/dL</td>
<td>&lt; 6.5 g/dL</td>
</tr>
<tr>
<td>(HIV POSITIVE ONLY)</td>
<td>5.24 – 6.23 mmol/L</td>
<td>4.62 – 5.23 mmol/L</td>
<td>4.03 – 4.61 mmol/L</td>
<td>&lt; 4.03 mmol/L</td>
</tr>
<tr>
<td>Adult and Pediatric ≥ 57 days</td>
<td>10.0 – 10.9 g/dL</td>
<td>9.0 – 9.9 g/dL</td>
<td>7.0 – 8.9 g/dL</td>
<td>&lt; 7.0 g/dL</td>
</tr>
<tr>
<td>(HIV NEGATIVE ONLY)</td>
<td>6.18 – 6.79 mmol/L</td>
<td>5.55 – 6.17 mmol/L</td>
<td>4.34 – 5.54 mmol/L</td>
<td>&lt; 4.34 mmol/L</td>
</tr>
<tr>
<td>OR Any decrease</td>
<td>2.5 – 3.4 g/dL</td>
<td>2.14 – 2.78 mmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infant*, 36 – 56 days</td>
<td>8.5 – 9.4 g/dL</td>
<td>7.0 – 8.4 g/dL</td>
<td>6.0 – 6.9 g/dL</td>
<td>&lt; 6.0 g/dL</td>
</tr>
<tr>
<td>(HIV POSITIVE OR NEGATIVE)</td>
<td>5.24 – 5.86 mmol/L</td>
<td>4.31 – 5.23 mmol/L</td>
<td>3.72 – 4.30 mmol/L</td>
<td>&lt; 3.72 mmol/L</td>
</tr>
<tr>
<td>Infant*, 22 – 35 days</td>
<td>9.5 – 10.5 g/dL</td>
<td>8.0 – 9.4 g/dL</td>
<td>7.0 – 7.9 g/dL</td>
<td>&lt; 7.0 g/dL</td>
</tr>
<tr>
<td>(HIV POSITIVE OR NEGATIVE)</td>
<td>5.87 – 6.54 mmol/L</td>
<td>4.93 – 5.86 mmol/L</td>
<td>4.34 – 4.92 mmol/L</td>
<td>&lt; 4.34 mmol/L</td>
</tr>
<tr>
<td>Infant*, ≤ 21 days</td>
<td>12.0 – 13.0 g/dL</td>
<td>10.0 – 11.9 g/dL</td>
<td>9.0 – 9.9 g/dL</td>
<td>&lt; 9.0 g/dL</td>
</tr>
<tr>
<td>(HIV POSITIVE OR NEGATIVE)</td>
<td>7.42 – 8.09 mmol/L</td>
<td>6.18 – 7.41 mmol/L</td>
<td>5.59 – 6.17 mmol/L</td>
<td>&lt; 5.59 mmol/L</td>
</tr>
<tr>
<td><strong>Correction:</strong> Parameter changed from “Infant &lt; 21 days” to “Infant ≤ 21 days”</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>International Normalized Ratio of prothrombin time (INR)</td>
<td>1.1 – 1.5 x ULN</td>
<td>1.6 – 2.0 x ULN</td>
<td>2.1 – 3.0 x ULN</td>
<td>&gt; 3.0 x ULN</td>
</tr>
<tr>
<td>Methemoglobin</td>
<td>5.0 – 10.0%</td>
<td>10.1 – 15.0%</td>
<td>15.1 – 20.0%</td>
<td>&gt; 20.0%</td>
</tr>
<tr>
<td>Prothrombin Time (PT)</td>
<td>1.1 – 1.25 x ULN</td>
<td>1.26 – 1.50 x ULN</td>
<td>1.51 – 3.00 x ULN</td>
<td>&gt; 3.00 x ULN</td>
</tr>
<tr>
<td>Partial Thromboplastin Time (PTT)</td>
<td>1.1 – 1.66 x ULN</td>
<td>1.67 – 2.33 x ULN</td>
<td>2.34 – 3.00 x ULN</td>
<td>&gt; 3.00 x ULN</td>
</tr>
<tr>
<td>Platelets, decreased</td>
<td>100,000 – 124,999/mm³</td>
<td>50,000 – 99,999/mm³</td>
<td>25,000 – 49,999/mm³</td>
<td>&lt; 25,000/mm³</td>
</tr>
<tr>
<td></td>
<td>100,000 x 10⁹ – 124,999 x 10⁹/L</td>
<td>50,000 x 10⁹ – 99,999 x 10⁹/L</td>
<td>25,000 x 10⁹ – 49,999 x 10⁹/L</td>
<td>&lt; 25,000 x 10⁹/L</td>
</tr>
<tr>
<td>WBC, decreased</td>
<td>2,000 – 2,500/mm³</td>
<td>1,500 – 1,999/mm³</td>
<td>1,000 – 1,499/mm³</td>
<td>&lt; 1,000/mm³</td>
</tr>
<tr>
<td></td>
<td>2,000 x 10⁹ – 2,500 x 10⁹/L</td>
<td>1,500 x 10⁹ – 1,999 x 10⁹/L</td>
<td>1,000 x 10⁹ – 1,499 x 10⁹/L</td>
<td>&lt; 1,000 x 10⁹/L</td>
</tr>
</tbody>
</table>

* Values are for term infants. Preterm infants should be assessed using local normal ranges.

† Use age and sex appropriate values (e.g., bilirubin).
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>CHEMISTRIES</td>
<td>Standard International Units are listed in italics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acidosis</td>
<td>NA</td>
<td>pH &lt; normal, but ≥ 7.3</td>
<td>pH &lt; 7.3 without life-threatening consequences</td>
<td>pH &lt; 7.3 with life-threatening consequences</td>
</tr>
<tr>
<td>Albumin, serum, low</td>
<td>3.0 g/dL – &lt; LLN 30 g/L – &lt; LLN</td>
<td>2.0 – 2.9 g/dL 20 – 29 g/L</td>
<td>&lt; 2.0 g/dL &lt; 20 g/L</td>
<td>NA</td>
</tr>
<tr>
<td>Alkaline Phosphatase</td>
<td>1.25 – 2.5 x ULN†</td>
<td>2.6 – 5.0 x ULN†</td>
<td>5.1 – 10.0 x ULN†</td>
<td>&gt; 10.0 x ULN†</td>
</tr>
<tr>
<td>Alkalosis</td>
<td>NA</td>
<td>pH &gt; normal, but ≤ 7.5</td>
<td>pH &gt; 7.5 without life-threatening consequences</td>
<td>pH &gt; 7.5 with life-threatening consequences</td>
</tr>
<tr>
<td>ALT (SGPT)</td>
<td>1.25 – 2.5 x ULN</td>
<td>2.6 – 5.0 x ULN</td>
<td>5.1 – 10.0 x ULN</td>
<td>&gt; 10.0 x ULN</td>
</tr>
<tr>
<td>AST (SGOT)</td>
<td>1.25 – 2.5 x ULN</td>
<td>2.6 – 5.0 x ULN</td>
<td>5.1 – 10.0 x ULN</td>
<td>&gt; 10.0 x ULN</td>
</tr>
<tr>
<td>Bicarbonate, serum, low</td>
<td>16.0 mEq/L – &lt; LLN 16.0 mmol/L – &lt; LLN</td>
<td>11.0 – 15.9 mEq/L 11.0 – 15.9 mmol/L</td>
<td>8.0 – 10.9 mEq/L 8.0 – 10.9 mmol/L</td>
<td>&lt; 8.0 mEq/L &lt; 8.0 mmol/L</td>
</tr>
<tr>
<td>Bilirubin (Total)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult and Pediatric &gt; 14 days</td>
<td>1.1 – 1.5 x ULN</td>
<td>1.6 – 2.5 x ULN</td>
<td>2.6 – 5.0 x ULN</td>
<td>&gt; 5.0 x ULN</td>
</tr>
<tr>
<td>Infant*, ≤ 14 days (non-hemolytic)</td>
<td>NA</td>
<td>20.0 – 25.0 mg/dL 342 – 428 µmol/L</td>
<td>25.1 – 30.0 mg/dL 429 – 513 µmol/L</td>
<td>&gt; 30.0 mg/dL &gt; 513.0 µmol/L</td>
</tr>
<tr>
<td>Infant*, ≤ 14 days (hemolytic)</td>
<td>NA</td>
<td>NA</td>
<td>20.0 – 25.0 mg/dL 342 – 428 µmol/L</td>
<td>&gt; 25.0 mg/dL &gt; 428 µmol/L</td>
</tr>
<tr>
<td>Calcium, serum, high</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult and Pediatric ≥ 7 days</td>
<td>10.6 – 11.5 mg/dL 2.65 – 2.88 mmol/L</td>
<td>11.6 – 12.5 mg/dL 2.89 – 3.13 mmol/L</td>
<td>12.6 – 13.5 mg/dL 3.14 – 3.38 mmol/L</td>
<td>&gt; 13.5 mg/dL &gt; 3.38 mmol/L</td>
</tr>
<tr>
<td>Infant*, &lt; 7 days</td>
<td>11.5 – 12.4 mg/dL 2.88 – 3.10 mmol/L</td>
<td>12.5 – 12.9 mg/dL 3.11 – 3.23 mmol/L</td>
<td>13.0 – 13.5 mg/dL 3.245 – 3.38 mmol/L</td>
<td>&gt; 13.5 mg/dL &gt; 3.38 mmol/L</td>
</tr>
<tr>
<td>Calcium, serum, low</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult and Pediatric ≥ 7 days</td>
<td>7.8 – 8.4 mg/dL 1.95 – 2.10 mmol/L</td>
<td>7.0 – 7.7 mg/dL 1.75 – 1.94 mmol/L</td>
<td>6.1 – 6.9 mg/dL 1.53 – 1.74 mmol/L</td>
<td>&lt; 6.1 mg/dL &lt; 1.53 mmol/L</td>
</tr>
<tr>
<td>Infant*, &lt; 7 days</td>
<td>6.5 – 7.5 mg/dL 1.63 – 1.88 mmol/L</td>
<td>6.0 – 6.4 mg/dL 1.50 – 1.62 mmol/L</td>
<td>5.50 – 5.90 mg/dL 1.38 – 1.51 mmol/L</td>
<td>&lt; 5.50 mg/dL &lt; 1.38 mmol/L</td>
</tr>
</tbody>
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</tr>
</thead>
<tbody>
<tr>
<td>Cardiac troponin I (cTnI)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Levels consistent with myocardial infarction or unstable angina as defined by the manufacturer</td>
</tr>
<tr>
<td>Cardiac troponin T (cTnT)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>≥ 0.20 ng/mL OR Levels consistent with myocardial infarction or unstable angina as defined by the manufacturer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Cholesterol (fasting)</strong></th>
<th><strong>Adult ≥ 18 years</strong></th>
<th><strong>Pediatric &lt; 18 years</strong></th>
<th><strong>Creatine Kinase</strong></th>
<th><strong>Creatinine</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>200 – 239 mg/dL</td>
<td>170 – 199 mg/dL</td>
<td>3.0 – 5.9 x ULN$^\dagger$</td>
<td>1.1 – 1.3 x ULN$^\dagger$</td>
</tr>
<tr>
<td></td>
<td>5.18 – 6.19 mmol/L</td>
<td>4.40 – 5.15 mmol/L</td>
<td>6.0 – 9.9 x ULN$^\dagger$</td>
<td>6.0 – 9.9 x ULN$^\dagger$</td>
</tr>
<tr>
<td></td>
<td>240 – 300 mg/dL</td>
<td>200 – 300 mg/dL</td>
<td>10.0 – 19.9 x ULN$^\dagger$</td>
<td>10.0 – 19.9 x ULN$^\dagger$</td>
</tr>
<tr>
<td></td>
<td>6.20 – 7.77 mmol/L</td>
<td>5.16 – 7.77 mmol/L</td>
<td>≥ 20.0 x ULN$^\dagger$</td>
<td>≥ 20.0 x ULN$^\dagger$</td>
</tr>
<tr>
<td></td>
<td>&gt; 300 mg/dL</td>
<td>&gt; 300 mg/dL</td>
<td>≥ 20.0 x ULN$^\dagger$</td>
<td>≥ 20.0 x ULN$^\dagger$</td>
</tr>
<tr>
<td></td>
<td>7.77 mmol/L</td>
<td>7.77 mmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NA</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Glucose, serum, high</strong></th>
<th><strong>Nonfasting</strong></th>
<th><strong>Fasting</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>116 – 160 mg/dL</td>
<td>110 – 125 mg/dL</td>
</tr>
<tr>
<td></td>
<td>6.44 – 8.85 mmol/L</td>
<td>6.11 – 6.94 mmol/L</td>
</tr>
<tr>
<td></td>
<td>161 – 250 mg/dL</td>
<td>126 – 250 mg/dL</td>
</tr>
<tr>
<td></td>
<td>8.89 – 13.88 mmol/L</td>
<td>6.95 – 13.88 mmol/L</td>
</tr>
<tr>
<td></td>
<td>251 – 500 mg/dL</td>
<td>251 – 500 mg/dL</td>
</tr>
<tr>
<td></td>
<td>13.89 – 27.75 mmol/L</td>
<td>13.89 – 27.75 mmol/L</td>
</tr>
<tr>
<td></td>
<td>&gt; 500 mg/dL</td>
<td>&gt; 500 mg/dL</td>
</tr>
<tr>
<td></td>
<td>&gt; 27.75 mmol/L</td>
<td>&gt; 27.75 mmol/L</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Glucose, serum, low</strong></th>
<th><strong>Adult and Pediatric ≥ 1 month</strong></th>
<th><em><em>Infant</em>, &lt; 1 month</em>*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>55 – 64 mg/dL</td>
<td>50 – 54 mg/dL</td>
</tr>
<tr>
<td></td>
<td>3.05 – 3.55 mmol/L</td>
<td>2.78 – 3.00 mmol/L</td>
</tr>
<tr>
<td></td>
<td>40 – 54 mg/dL</td>
<td>40 – 49 mg/dL</td>
</tr>
<tr>
<td></td>
<td>2.22 – 3.06 mmol/L</td>
<td>2.22 – 2.77 mmol/L</td>
</tr>
<tr>
<td></td>
<td>30 – 39 mg/dL</td>
<td>30 – 39 mg/dL</td>
</tr>
<tr>
<td></td>
<td>1.67 – 2.33 mmol/L</td>
<td>1.67 – 2.21 mmol/L</td>
</tr>
<tr>
<td></td>
<td>&lt; 30 mg/dL</td>
<td>&lt; 30 mg/dL</td>
</tr>
<tr>
<td></td>
<td>&lt; 1.67 mmol/L</td>
<td>&lt; 1.67 mmol/L</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Lactate</strong></th>
<th><strong>ULN - &lt; 2.0 x ULN without acidosis</strong></th>
<th><strong>≥ 2.0 x ULN without acidosis</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Increased lactate with pH &lt; 7.3 without life-threatening consequences</td>
<td>Increased lactate with pH &lt; 7.3 with life-threatening consequences</td>
</tr>
</tbody>
</table>

* Values are for term infants. Preterm infants should be assessed using local normal ranges.
† Use age and sex appropriate values (e.g., bilirubin).
DIVISION OF AIDS TABLE FOR GRADING THE SEVERITY OF ADULT AND PEDIATRIC ADVERSE EVENTS
VERSION 1.0, DECEMBER, 2004; CLARIFICATION AUGUST 2009

<table>
<thead>
<tr>
<th>LABORATORY</th>
<th>GRADE 1 MILD</th>
<th>GRADE 2 MODERATE</th>
<th>GRADE 3 SEVERE</th>
<th>GRADE 4 POTENTIALLY LIFE-THREATENING</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL cholesterol (fasting)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult ≥ 18 years</td>
<td>130 – 159 mg/dL</td>
<td>160 – 190 mg/dL</td>
<td>≥ 190 mg/dL</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>3.37 – 4.12 mmol/L</td>
<td>4.13 – 4.90 mmol/L</td>
<td>≥ 4.91 mmol/L</td>
<td></td>
</tr>
<tr>
<td>Pediatric &gt; 2 - &lt; 18 years</td>
<td>110 – 129 mg/dL</td>
<td>130 – 189 mg/dL</td>
<td>≥ 190 mg/dL</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>2.85 – 3.34 mmol/L</td>
<td>3.35 – 4.90 mmol/L</td>
<td>≥ 4.91 mmol/L</td>
<td></td>
</tr>
<tr>
<td>Lipase</td>
<td>1.1 – 1.5 x ULN</td>
<td>1.6 – 3.0 x ULN</td>
<td>3.1 – 5.0 x ULN</td>
<td>&gt; 5.0 x ULN</td>
</tr>
<tr>
<td>Magnesium, serum, low</td>
<td>1.2 – 1.4 mEq/L</td>
<td>0.9 – 1.1 mEq/L</td>
<td>0.6 – 0.8 mEq/L</td>
<td>&lt; 0.60 mEq/L</td>
</tr>
<tr>
<td></td>
<td>0.60 – 0.70 mmol/L</td>
<td>0.45 – 0.59 mmol/L</td>
<td>0.30 – 0.44 mmol/L</td>
<td>&lt; 0.30 mmol/L</td>
</tr>
<tr>
<td>Pancreatic amylase</td>
<td>1.1 – 1.5 x ULN</td>
<td>1.6 – 2.0 x ULN</td>
<td>2.1 – 5.0 x ULN</td>
<td>&gt; 5.0 x ULN</td>
</tr>
<tr>
<td>Phosphate, serum, low</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult and Pediatric &gt; 14 years</td>
<td>2.5 mg/dL – &lt; LLN</td>
<td>2.0 – 2.4 mg/dL</td>
<td>1.0 – 1.9 mg/dL</td>
<td>&lt; 1.00 mg/dL</td>
</tr>
<tr>
<td></td>
<td>0.81 mmol/L – &lt; LLN</td>
<td>0.65 – 0.80 mmol/L</td>
<td>0.32 – 0.64 mmol/L</td>
<td>&lt; 0.32 mmol/L</td>
</tr>
<tr>
<td>Pediatric 1 year – 14 years</td>
<td>3.0 – 3.5 mg/dL</td>
<td>2.5 – 2.9 mg/dL</td>
<td>1.5 – 2.4 mg/dL</td>
<td>&lt; 1.50 mg/dL</td>
</tr>
<tr>
<td></td>
<td>0.97 – 1.13 mmol/L</td>
<td>0.81 – 0.96 mmol/L</td>
<td>0.48 – 0.80 mmol/L</td>
<td>&lt; 0.48 mmol/L</td>
</tr>
<tr>
<td>Pediatric &lt; 1 year</td>
<td>3.5 – 4.5 mg/dL</td>
<td>2.5 – 3.4 mg/dL</td>
<td>1.5 – 2.4 mg/dL</td>
<td>&lt; 1.50 mg/dL</td>
</tr>
<tr>
<td></td>
<td>1.13 – 1.45 mmol/L</td>
<td>0.81 – 1.12 mmol/L</td>
<td>0.48 – 0.80 mmol/L</td>
<td>&lt; 0.48 mmol/L</td>
</tr>
<tr>
<td>Potassium, serum, high</td>
<td>5.6 – 6.0 mEq/L</td>
<td>6.1 – 6.5 mEq/L</td>
<td>6.6 – 7.0 mEq/L</td>
<td>≥ 7.0 mEq/L</td>
</tr>
<tr>
<td></td>
<td>5.6 – 6.0 mmol/L</td>
<td>6.1 – 6.5 mmol/L</td>
<td>6.6 – 7.0 mmol/L</td>
<td>≥ 7.0 mmol/L</td>
</tr>
<tr>
<td>Potassium, serum, low</td>
<td>3.0 – 3.4 mEq/L</td>
<td>2.5 – 2.9 mEq/L</td>
<td>2.0 – 2.4 mEq/L</td>
<td>&lt; 2.0 mEq/L</td>
</tr>
<tr>
<td></td>
<td>3.0 – 3.4 mmol/L</td>
<td>2.5 – 2.9 mmol/L</td>
<td>2.0 – 2.4 mEq/L</td>
<td>&lt; 2.0 mEq/L</td>
</tr>
<tr>
<td>Sodium, serum, high</td>
<td>146 – 150 mEq/L</td>
<td>151 – 154 mEq/L</td>
<td>155 – 159 mEq/L</td>
<td>≥ 160 mEq/L</td>
</tr>
<tr>
<td></td>
<td>146 – 150 mmol/L</td>
<td>151 – 154 mmol/L</td>
<td>155 – 159 mmol/L</td>
<td>≥ 160 mmol/L</td>
</tr>
<tr>
<td>Sodium, serum, low</td>
<td>130 – 135 mEq/L</td>
<td>125 – 129 mEq/L</td>
<td>121 – 124 mEq/L</td>
<td>≤ 120 mEq/L</td>
</tr>
<tr>
<td></td>
<td>130 – 135 mmol/L</td>
<td>125 – 129 mmol/L</td>
<td>121 – 124 mmol/L</td>
<td>≤ 120 mmol/L</td>
</tr>
<tr>
<td>Triglycerides (fasting)</td>
<td>NA</td>
<td>500 – 750 mg/dL</td>
<td>751 – 1,200 mg/dL</td>
<td>&gt; 1,200 mg/dL</td>
</tr>
<tr>
<td></td>
<td>5.65 – 8.48 mmol/L</td>
<td>8.49 – 13.56 mmol/L</td>
<td>&gt; 13.56 mmol/L</td>
<td></td>
</tr>
</tbody>
</table>

* Values are for term infants. Preterm infants should be assessed using local normal ranges.
† Use age and sex appropriate values (e.g., bilirubin).
### LABORATORY

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>GRADE 1 MILD</th>
<th>GRADE 2 MODERATE</th>
<th>GRADE 3 SEVERE</th>
<th>GRADE 4 POTENTIALLY LIFE-THREATENING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uric acid</td>
<td>7.5 – 10.0 mg/dL 0.45 – 0.59 mmol/L</td>
<td>10.1 – 12.0 mg/dL 0.60 – 0.71 mmol/L</td>
<td>12.1 – 15.0 mg/dL 0.72 – 0.89 mmol/L</td>
<td>&gt; 15.0 mg/dL &gt; 0.89 mmol/L</td>
</tr>
</tbody>
</table>

### URINALYSIS  
*Standard International Units are listed in italics*

<table>
<thead>
<tr>
<th></th>
<th>GRADE 1 MILD</th>
<th>GRADE 2 MODERATE</th>
<th>GRADE 3 SEVERE</th>
<th>GRADE 4 POTENTIALLY LIFE-THREATENING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematuria (microscopic)</td>
<td>6 – 10 RBC/HPF</td>
<td>&gt; 10 RBC/HPF</td>
<td>Gross, with or without clots OR with RBC casts</td>
<td>Transfusion indicated</td>
</tr>
<tr>
<td>Proteinuria, random collection</td>
<td>1 +</td>
<td>2 – 3 +</td>
<td>4 +</td>
<td>NA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proteinuria, 24 hour collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult and Pediatric ≥ 10 years</td>
</tr>
<tr>
<td>200 – 999 mg/24 h 0.200 – 0.999 g/d</td>
</tr>
<tr>
<td>1,000 – 1,999 mg/24 h 1.000 – 1.999 g/d</td>
</tr>
<tr>
<td>2,000 – 3,500 mg/24 h 2.000 – 3.500 g/d</td>
</tr>
<tr>
<td>&gt; 3,500 mg/24 h &gt; 3.500 g/d</td>
</tr>
<tr>
<td>Pediatric &gt; 3 mo - &lt; 10 years</td>
</tr>
<tr>
<td>201 – 499 mg/m²/24 h 0.201 – 0.499 g/d</td>
</tr>
<tr>
<td>500 – 799 mg/m²/24 h 0.500 – 0.799 g/d</td>
</tr>
<tr>
<td>800 – 1,000 mg/m²/24 h 0.800 – 1.000 g/d</td>
</tr>
<tr>
<td>&gt; 1,000 mg/ m²/24 h &gt; 1.000 g/d</td>
</tr>
</tbody>
</table>

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† Use age and sex appropriate values (e.g., bilirubin).