**Toxicity Evaluation:**

**Version 5.0**

Please evaluate each toxicity experienced by patient, indicating the worst toxicity experienced by patient this reporting period. Be sure to indicate relationship to study Rx.

\*Criteria for determining relationship to study Rx.

1= not related 2= unlikely 3= possibly 4= probably 5= definitely

| TOXICITY | **ir** | **0** | **1** | **2** | **3** | **4** |
| --- | --- | --- | --- | --- | --- | --- |
| Anemia **\*Rel to Rx 1 2 3 4 5** |  |  | Hemoglobin (Hgb) <LLN - 10.0 g/dL; <LLN - 6.2 mmol/L; <LLN - 100 g/L | Hgb <10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L | Hgb <8.0 - 6.5 g/dL; <4.9 - 4.0 mmol/L; <80 - 65 g/L; transfusion indicated | Life-threatening consequences; urgent intervention indicated |
| **Neutrophil count decreased**  **\*Rel to Rx 1 2 3 4 5** |  |  | <LLN - 1500/mm3; <LLN - 1.5 x 10e9 /L | <1500 - 1000/mm3; <1.5 - 1.0 x 10e9 /L | <1000 - 500/mm3; <1.0 - 0.5 x 10e9 /L | <500/mm3; <0.5 x 10e9 /L |
| **Platelet count decreased**  **\*Rel to Rx 1 2 3 4 5** |  |  | <LLN - 75,000/mm3; <LLN - 75.0 x 10e9 /L | <75,000 - 50,000/mm3; <75.0 - 50.0 x 10e9 /L | <50,000 - 25,000/mm3; <50.0 - 25.0 x 10e9 /L | <25,000/mm3; <25.0 x 10e9 /L |
| **White blood cell decreased**  **\*Rel to Rx 1 2 3 4 5** |  |  | <LLN - 3000/mm3; <LLN - 3.0 x 10e9 /L | <3000 - 2000/mm3; <3.0 - 2.0 x 10e9 /L | <2000 - 1000/mm3; <2.0 - 1.0 x 10e9 /L | <1000/mm3; <1.0 x 10e9 /L |
| **Constipation**  **\*Rel to Rx 1 2 3 4 5** |  |  | Occasional or intermittent symptoms; occasional use of  stool softeners, laxatives, dietary modification, or enema | Persistent symptoms with regular use of laxatives or enemas; limiting instrumental  ADL | Obstipation with manual  evacuation indicated; limiting self care ADL | Life-threatening  consequences; urgent  intervention indicated |
| **Diarrhea**  **\*Rel to Rx 1 2 3 4 5** |  |  | Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline | Increase of 4 - 6 stools per day over baseline; moderate  increase in ostomy output compared to baseline; limiting instrumental ADL | Increase of >=7 stools per day over baseline; incontinence; hospitalization indicated;  severe increase in ostomy  output compared to baseline; limiting self care ADL | Life-threatening  consequences; urgent  intervention indicated |
| **Nausea**  **\*Rel to Rx 1 2 3 4 5** |  |  | Loss of appetite without alteration in eating habits | Oral intake decreased without significant weight loss, dehydration or malnutrition | Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated | - |
| **Vomiting**  **\*Rel to Rx 1 2 3 4 5** |  |  | Intervention not indicated | Outpatient IV hydration; medical intervention indicated | Tube feeding, TPN or hospitalization indicated | Life-threatening  consequences |
| **Edema limbs**  **\*Rel to Rx 1 2 3 4 5** |  |  | 5 - 10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection | >10 - 30% inter-limb  discrepancy in volume or circumference at point of greatest visible difference;  readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation  from normal anatomic  contour; limiting instrumental ADL | >30% inter-limb discrepancy in volume; gross deviation from normal anatomic contour; limiting self care ADL | - |
| **Fatigue**  **\*Rel to Rx 1 2 3 4 5** |  |  | Fatigue relieved by rest | Fatigue not relieved by rest; limiting instrumental ADL | Fatigue not relieved by rest, limiting self care ADL | - |
| **Fever**  **\*Rel to Rx 1 2 3 4 5** |  |  | 38.0 - 39.0 degrees C (100.4 - 102.2 degrees F) | >39.0 - 40.0 degrees C (102.3 - 104.0 degrees F) | >40.0 degrees C (>104.0  degrees F) for <=24 hrs | >40.0 degrees C (>104.0 degrees F) for >24 hrs |
| **Anorexia**  **\*Rel to Rx 1 2 3 4 5** |  |  | Loss of appetite without alteration in eating habits | Oral intake altered without significant weight loss or  malnutrition; oral nutritional supplements indicated | Associated with significant  weight loss or malnutrition  (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated | Life-threatening  consequences; urgent  intervention indicated |
| **Peripheral motor neuropathy**  **\*Rel to Rx 1 2 3 4 5** |  |  | Asymptomatic; clinical or diagnostic observations only; | Moderate symptoms; limiting instrumental ADL | Severe symptoms; limiting self care ADL | Life-threatening  consequences; urgent  intervention indicated |
| **Peripheral sensory neuropathy**  **\*Rel to Rx 1 2 3 4 5** |  |  | Asymptomatic; | Moderate symptoms; limiting instrumental ADL | Severe symptoms; limiting self care ADL | Life-threatening  consequences; urgent  intervention indicated |
| **Extremity Pain: \_\_\_\_\_**  **\*Rel to Rx 1 2 3 4 5** |  |  | Mild pain | Moderate pain; limiting instrumental ADL | Severe pain limiging self care ADL | --- |
| **Pneumonia(lung inf)**  **\*Rel to Rx 1 2 3 4 5** |  |  | -------- | Moderate symptoms; oral intervention indicated. | IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated | Life-threatening consequences; urgent intervention indicated |
| **Lymphocyte decrease**  **\*Rel to Rx 1 2 3 4 5** |  |  | <LLN – 800/mm3; < LLN – o.8 x10e9/L | < 800-500/mm3 | <500 – 200/mm3 | <200/mm3 |
| **Hyponatremia**  **\*Rel to Rx 1 2 3 4 5** |  |  | <LLN – 130 mmol/L | 125-129 mmol/L and asymptomatic | 125-129 mmol/L symptomatic; 120-124 mmol/L regardless of symptoms | <120 mmol/L; life-threatening consequences |
| **Hyperkalemia**  **\*Rel to Rx 1 2 3 4 5** |  |  | ULN – 5.5 mmol/L | >5.5 – 6.0 mmol/L | >6.0 – 7.0 mmol/L; hospitalization indicated | > 7.0 mmol/L; life-threatening consequences |
| **Heart Failure**  **\*Rel to Rx 1 2 3 4 5** |  |  | Asymptomatic with laboratory (e.g., BNP ) or cardiac imaging abnormalities | Symptoms with mild to moderate activity or exertion | Symptoms at rest or with minimal activity or exertion; hospitalization; new onset of symptoms | Life-threatening consequences; urgent intervention indicated |
| **Hypocalcemia**  **\*Rel to Rx 1 2 3 4 5** |  |  | Corrected serum calcium of <LLN - 8.0 mg/dL; <LLN - 2.0 mmol/L; Ionized calcium <LLN - 1.0 mmol/L | Corrected serum calcium of <8.0 – 7 mg/dL; <2.0-1.75 mmol/L; Ionized calcium < 1.0-0.9 mmol/L; symptomatic | Corrected serum calcium of < 7.0-6.0 mg/dL; < 1.75-1.5 mmol?L; ionized calcium < 9.0 – 0.8 mmol?L; hospitalization indicated | Corrected serum calcium of <6.0 mg/dL; < 1.5 mmol/L; Ionized calcium <0.8 mmol/L; life threatening consequences |
| **Creatinine increase**  **\*Rel to Rx 1 2 3 4 5** |  |  | >ULN - 1.5 x ULN | >1.5 – 3.0 x baseline;>1.5-3.0 x ULN | >3.0 baseline; > 3.0-6.0 x ULN | > 6.0 X ULN |
| **Dyspnea**  **\*Rel to Rx 1 2 3 4 5** |  |  | Shortness of breath with moderate exertion | Shortness of breath with minimal exertion; limiting instrumental ADL | Shortness of breath at rest; limiting self care ADL | Life-threatening consequences; urgent intervention indicated |
| **Albumin decrease**  **\*Rel to Rx 1 2 3 4 5** |  |  | <LLN – 3.0 g/dL; <LLN – 30 g/L | <3 - 2 g/dL; <30 - 20 g/L | <2 g/dL; <20 g/L | Life-threatening consequences; urgent intervention indicated |
| **Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **\*Rel to Rx 1 2 3 4 5** |  |  | Mild | Moderate | Severe | Life-threatening |
| **Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **\*Rel to Rx 1 2 3 4 5** |  |  | Mild | Moderate | Severe | Life-threatening |
| **Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **\*Rel to Rx 1 2 3 4 5** |  |  | Mild | Moderate | Severe | Life-threatening |
| **Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **\*Rel to Rx 1 2 3 4 5** |  |  | Mild | Moderate | Severe | Life-threatening |

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| --- | --- | --- | --- | --- | --- |
| Performance  Status | 0 | 1 | 2 | 3 | 4 |
|  | Asymptomatic and fully active | Symptomatic; fully ambulatory; restricted in strenuous activity | Symptomatic; ambulatory; capable of self-care; > 50% of waking hours spent out of bed | Symptomatic; limited self care; > 50% of time in bed, but not bedridden | Completely disabled; no self-care; bedridden |

Other significant information: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Contraindicated medications and supplements specific to this protocol have been reviewed with this specific patient, and he/ she agrees to abide by the prohibitions and cautions.** **Y N NA**

**Baseline: Protocol defined requirements for use of contraception have been discussed with this patient, and he/she agrees. Y N**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_

Physician Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_