General Treatment Protocol for the use of Intravenous Ascorbic Acid as used by Bastyr University Clinical Research Center (BCRC) and Anderson Medical Specialty Associates

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General Schedule:

- Treatment Frequency:
    - IV # 1- 15: one to three times weekly
    - Based on our internal data review regarding assessment of efficacy our protocol the data showed an inability to assess positive or negative response until 12 to 15 IVC treatments were achieved.
- Intake Visit:
    - Informed Consent
    - Pre-Testing: CBC + Reticulocyte count, CMP aka Chem 14 (ALB/T.Prot/BUN/CRE/AlkPhos Glucose/T.Bili/K/Ca/Cl/CO2/Na/ALT/AST) , G6PD; (And – per situation - NK Activity, CTC, Tumor Markers, Imaging)
    - If Calcium or Potassium are hypo or hyper consider IVC formula alteration to compensate.
- Criteria for assessment of performance of IVC:
    - At intake clinical decisions should be made regarding metrics to be used as measurement of regression, stabilization or progression of disease.
        - This can include any positive findings present at the outset of therapy, including but not limited to:
            - Tumor markers
            - PET-CT
            - Other Imaging
            - Physical Exam Findings
            - Patient signs and symptoms directly attributed to the cancer
    - This assessment can also include general quality of life metrics as partial or entire criteria.
- IV #1: PARQ Conference, then IVC 25 Grams
- IV #2: IVC 50 Grams

- IV #3: IVC 75 Grams, Then post IV (drawn directly after IV) Serum / Plasma ASC level
    - If ASC level = > 350 - 400 mg/dL: continue 75 gram IVC
    - If ASC level < 350 - 400 mg/dL: increase to 100 gram IVC and re test ASC level
    - NOTE:
        - Some centers use a glucometer to estimate ascorbate concentrations
        - Some centers do not run ascorbate levels and arbitrarily set the treatment dose at 25 to 100 grams.
- IV #4 forward = 75 grams or higher (per testing).
    - After 3 – 6 IVC doses Re check BMP (electrolytes, BUN-CRE, GFR, Gluc) + Bilirubin (Or order a Chem-23) and CBC + Reticulocyte count, drawn **before the IV.**
    - If needed re-check LFT's etc.
    - If Na, K, Ca altered: consider oral or IV addition. Check GFR. If BMP altered re-check in 3-4 Tx.
- At Tx 12-15:
    - Re test NK Fct, Markers etc
    - Consider second round of IVC 2X weekly or Maintenance at 1 Tx weekly.
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Causes to clear further treatment with IV services Chief or Fellow:

- Electrolyte change from baseline to frank hypo or hyper state
- Muscle spasm / Cardiac rhythm disturbance during IV
- Anemia coupled with:
    - Increased Bilirubin and/or Increased reticulocytes [Need to rule out hemolysis]
    - Suppressed RDW (<13) or WBC below 2.0 [Need to consider marrow suppression]
- GFR decrease of greater than 10 points OR below 40

BIORC /AMSA – IV Therapy Intervention Plan and Flow

Goals: Quality of Life Improvement – Oncologic Therapy Augmentation – Improved Survival