

# CHOA Clinical Trial Master List

## **MULTIPLE MYELOMA**

<b>Amgen 20170596: An Open-label Phase 4 Study of Carfilzomib (Kyprolis) Plus Dexamethasone To Assess Tolerability and Adherence in Subjects With Relapsed or Refractory Multiple Myeloma at US Community Oncology Centers</b>	
<b>Sponsor:</b> Amgen <b>**Contract negotiations**</b>	Therapy Line: <b>Relapsed/Refractory</b> Drug Classification:
<b>Principal Investigator:</b> George F. Geils, Jr., MD	<b>CRC:</b>
<b>Basic Enrollment Information Criteria:</b> Relapsed MM after last treatment or refractory while receiving non-proteasome Inhibitor therapy. Measurable disease with at least 1 of the following assessed within 21 days prior to enrollment: <ul style="list-style-type: none"><li>• immunoglobulin G (IgG) MM: serum monoclonal protein (M-protein) level <math>\geq 1.0</math> g/dL</li><li>• IgA, IgD, IgE multiple myeloma: serum M-protein level <math>\geq 0.5</math> g/dL</li><li>• urine M-protein <math>\geq 200</math> mg per 24 hours</li><li>• in subjects without detectable serum or urine M-protein, serum free light chain (SFLC) <math>\geq 100</math> mg/L (involved light chain) and an abnormal serum kappa lambda ratio.</li></ul> (ECOG PS) of 0 to 1. Subjects must have at least partial response (PR) to at least 1 line of prior therapy. Subjects must have received at least 1 but not more than 3 prior lines of therapy for MM (induction therapy followed by stem cell transplant and consolidation/maintenance therapy will be considered as 1 line of therapy).	
<b>Exclusion Criteria:</b> Waldenström macroglobulinemia. Multiple myeloma of IgM subtype. POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes). History of plasma cell leukemia. Myelodysplastic syndrome. History of other malignancy within the past 5 years. Immunotherapy within 21 days prior to enrollment. Chemotherapy with approved anticancer therapeutic within 21 days prior to enrollment.	