PI:
Sponsor:
Protocol Number:
Protocol Title:

The billing coverage analysis is intended as a general guideline for use in determining which items and services are allowed to be billed to insurance based on current benefit policies, coverage determination, coverage decisions, and federal guidelines. All items and services billed to insurance must be supported by medical necessity in the clinical documentation and may not be limited to what appears on the billing grid. The clinical needs of the individual patient and the judgment of the clinical provider ultimately determine medical necessity.

1 Cycle = X Days

Visit Assessments	Screening	Cycle 1	Cycle 2	Cycle 3	End of Treatment	Follow-Up	Comments
Informed Consnet	TE						Bill sponsor for time and effort only.
Inclusion/Exclusion	TE						Bill sponsor for time and effort only.
Complete Blood Count		M	M	M	M		Billable to insurance as this is conventional care per the PI.
Comprehensive Metabolic Panel		M	M	M	M		Billable to insurance as this is conventional care per the PI.
Radiological Assessments	INV						Invoiceable to sponsor.
Study Drug Administration		M	M	M	M		Bill to insurance as this is required solely for the provision of the investigational item. ***Coverage supported by NCD 310.1 - Routine Costs in Clinical Trials.***
Quality of Life Assessments		TE	TE	TE	TE		Bill sponsor for time and effort only.

KEY
NA = Bundled with another payment.
M = Bill to Medicare or other insurance
NB = Not Billable to anyone.
S = Charged to study fund.
INV = Invoiceable to sponsor.
TE = Bill for time and effort only (Items and services not associated with a CPT/HCPCs code).
INV/TE = Invoiceable to sponsor for time and effort only (i.e. optional central lab)