Samaritan Health Plans	Medical Coverage Policy

SAHP	IHP	SGC	LGC	SC	ADMIN
X	X	X	X	X	

SHPMCP-021 Edaravone (Radicava)	**Effective Date: 11/08/2018**
	Last Revision/Review Date:
	Dissemination Date: 11/14/2018
	Required Review Date: 11/08/2020

DISCLAIMER

Samaritan Health Plans (SHP) Medical Coverage Policies (SHPMCP) are intended to facilitate the Utilization Management process. It expresses Samaritan Health Plan's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this SHPMCP and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or, for Medicare and Medicaid members, by the Centers for Medicare & Medicaid Services (CMS). CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from a current National Coverage Determination (NCD) or Local Coverage Determination (LCD) will generally be followed by SHP for all Medicare members.

Samaritan Health Plan Medical Coverage Policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment. Samaritan Health Plans may also use tools developed by third parties, such as MCG™ Health, to assist us in administering health benefits. MCG™ Health Ambulatory Care Guidelines are intended to be used in connection with the independent professional medical judgement of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BACKGROUND

Radicava is a new or emerging therapy for selected patients with Amyotrophic Lateral Sclerosis which was approved by the FDA on May 5, 2017.

POLICY

Samaritan Health Plans considers Radicava (edaravone) medically necessary for the treatment of amyotrophic lateral sclerosis (ALS) in patients who meet all of the following criteria:

I. For initial therapy, all of the following:

A. Medical records submitted support the diagnosis of "definite" or "probable" ALS per the EL Escorial/revised Airlie House diagnostic criteria, and prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS; and
   i. Medical records may include but are not limited to:
      1. Chart notes
      2. Previous medical history
      3. Diagnostic testing including imaging, nerve conduction studies, laboratory values
B. Submission of the most recent ALS Functional Rating Scale-Revised (ALSFRS-R) score confirming that the patient has scores $\geq$ 2 in all items of the ALSFRS-R criteria at the start of treatment; and
C. Medical records submitted confirming that the patient has a % forced vital capacity (%FVC) > 80% at the start of treatment; and
D. Radicava dosing for ALS is in accordance with the United States Food and Drug Administration approved labeling; and
E. Age > 20 years; and
F. Initial authorization will be for no more than 6 cycles (64 doses over 168 days).

II. For continuation therapy, all of the following:
A. Diagnosis of "definite" or "probable" ALS per the EL Escorial/revised Airlie House diagnostic criteria, and prescribed by, or in conjunction with, a neurologist with expertise in the diagnosis of ALS; and
B. Patient is currently receiving Radicava therapy; and
C. Patient is not dependent on invasive ventilation or tracheostomy; and
D. Radicava dosing for ALS is in accordance with the United States Food and Drug Administration approved labeling; and
E. Age > 20 years; and
F. Authorization will be for no more than 6 cycles (60 doses over 168 days).

III. Samaritan Health Plans considers Edaravone experimental and investigational for the following (not an all-inclusive list):
A. Acute ischemic stroke
B. Choroidal neovascularization
C. Intra-cerebral hemorrhage
D. Myocardial damage after ischemia and re-perfusion
E. Nephropathy
F. Osteoarthritis

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Required Review Date:			
Revision #	Approved By / Date	Policy Owner Approved / Date	Revision Description
1	11/08/2018	Medical Policy Review Committee	New policy
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