STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE - TARPEYO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUDESONIDE	TARPEYO		51745	GPI-14 (22100012006520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by a renal biopsy
   - The patient is currently on an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) at maximum tolerated dose for at least three months OR has a contraindication to both
   - The patient has a progressively declining glomerular filtration rate (GFR) and/or worsening proteinuria (e.g., >1 gram protein/24-hour urine collection or UPCR [urine protein to creatinine ratio] ≥1 g/g)
   - The patient had a trial of or contraindication to one generic systemic corticosteroid therapy (e.g., oral prednisone, oral prednisolone)

   If yes, **approve for 9 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for approval:
   A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
   D. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
   E. You are currently on an angiotensin converting enzyme inhibitor (ACE-I: a type of drug used to protect kidneys such as benazepril, lisinopril, etc.) or an angiotensin receptor blocker (ARB: a type of drug used to protect kidneys such as losartan, valsartan, etc.) at maximum tolerated dose for at least three months OR have a contraindication (harmful for) to both

   (Initial denial text continued on the next page)

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BUDESONIDE – TARPEYO

INITIAL CRITERIA (CONTINUED)

F. You have a progressively declining glomerular filtration rate (GFR: a tool for evaluating kidney function) and/or worsening proteinuria (such as greater than 1 gram protein in a 24-hour urine collection or greater than or equal to 1g/g urine protein to creatinine ratio [UPCR: test that measures the amount of protein in urine])
G. You had a trial of or contraindication to one generic systemic corticosteroid therapy (such as oral prednisone, oral prednisolone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) and meet **ONE** of the following criteria?
   - The patient has improved or stable kidney function compared to baseline
   - The patient has had a reduction in proteinuria

   If yes, **approve for 9 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for renewal:
   A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   B. You have improved or stable kidney function compared to baseline OR a reduction in proteinuria

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BUDESONIDE – TARPEYO

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tarpeyo.

REFERENCES

- Tarpeyo [Prescribing Information]. Stockholm, Sweden: Calliditas Therapeutics, Inc.; December 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Created: 01/22
Commercial Effective: 01/07/22 Client Approval: P&T Approval: 07/21

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