



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SILDENAFIL SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILDENAFIL CITRATE	REVATIO, LIQREV, SILDENAFIL CITRATE		33186 54078	GPI-14 (40143060102020, 40143060101825)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group I) and meet **ALL** of the following criteria?
 - The patient is 1 to 17 years of age
 - The request is for Revatio (sildenafil) suspension
 - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
 - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
 - The patient is NOT concurrently taking guanylate cyclase stimulators (e.g., Adempas [riociguat])
 - The patient is unable to swallow pills and has tried crushed sildenafil tablets

If yes, continue to #2.

If no, continue to #3.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
 - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
 - Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
 - Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #14.93mL per day.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) 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 cardiologist or pulmonologist
 - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
 - The patient is NOT concurrently taking guanylate cyclase stimulators (e.g., Adempas [riociguat])

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
- Mean pulmonary artery pressure (PAP) greater than 20 mmHg
 - Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
 - Pulmonary vascular resistance (PVR) greater than 2 Wood units

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the request for **Revatio (sildenafil)** suspension **AND** the patient meets the following criterion?
- The patient is unable to swallow pills and has tried crushed sildenafil tablets

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #26.13mL per day.**

If no, continue to #6.

6. Is the request for **Liqrev** suspension and the patient meets **ALL** of the following criteria?
- The patient is unable to swallow Revatio (sildenafil) tablet
 - The patient had a trial of generic sildenafil powder for suspension

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #8.13 mL per day.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

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 **SILDENAFIL SUSPENSION (Revatio, Liqrev)** requires the following rule(s) be met for approval:

- A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO Group 1: a way to classify the severity of disease)
- B. **If you are 1 to 17 years of age, approval also requires:**
 - 1. You are requesting Revatio (sildenafil) suspension
 - 2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
 - 3. There is documentation (such as chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on all of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
 - a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
 - b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
 - c. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
 - 4. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
 - 5. You are NOT concurrently (at the same time) taking guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])
 - 6. You are unable to swallow pills AND you have tried crushed sildenafil tablets
- C. **If you are 18 years of age or older, approval also requires:**
 - 1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
 - 2. There is documentation (such as chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on all of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
 - a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
 - b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
 - c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
 - 3. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
 - 4. You are NOT concurrently (at the same time) taking guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])

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INITIAL CRITERIA (CONTINUED)

5. If you are requesting Revatio (sildenafil) suspension, you are unable to swallow pills AND you have tried crushed sildenafil tablets
6. If you are requesting Liqrev suspension, you are unable to swallow Revatio (sildenafil) tablet AND you have tried generic sildenafil powder for suspension

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 pulmonary arterial hypertension (PAH) (WHO Group I) and meet **ALL** of the following criteria?
 - The patient is 1 to 17 years old
 - The request is for Revatio (sildenafil) suspension
 - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
 - The patient is NOT concurrently taking guanylate cyclase stimulators (e.g., Adempas [riociguat])

If yes, continue to #2.

If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
 - The patient has shown improvement from baseline in 6-minute walk distance test
 - The patient remains stable from baseline in the 6-minute walk distance test with a stable or improved WHO functional class (WHO-FC)
 - The patient cannot perform exercise testing and is stable or improving on treatment

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #14.93mL per day.**
If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
 - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
 - The patient is NOT concurrently taking guanylate cyclase stimulators (e.g., Adempas [riociguat])
 - The patient has shown improvement from baseline in the 6-minute walk distance test OR remains stable from baseline in the 6-minute walk distance test with a stable or improved WHO functional class

If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**

- **Revatio (sildenafil): #26.13mL per day.**
- **Liqrev (sildenafil): #8.13mL 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 **SILDENAFIL SUSPENSION (Revatio, Liqrev)** requires the following rule(s) be met for renewal:

- A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO) Group 1 (a way to classify the severity of disease)
- B. **If you are 1 to 17 years of age, approval also requires:**
1. You are requesting Revatio (sildenafil) suspension
 2. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
 3. You are NOT concurrently (at the same time) taking guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])
 4. You meet ONE of the following criteria:
 - a. You have shown improvement from baseline in the 6-minute walk distance test
 - b. You remain stable from baseline in the 6-minute walk distance test with a stable or improved World Health Organization functional class (WHO-FC: a way to classify how limited you are during physical activity)
 - c. You cannot perform exercise testing and are stable or improving on treatment

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RENEWAL CRITERIA (CONTINUED)

C. If you are 18 years of age or older, approval also requires:

1. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
2. You are NOT concurrently (at the same time) taking guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])
3. You have shown improvement from baseline in the 6-minute walk distance test OR remain stable from baseline in the 6-minute walk distance test with a stable or improved World Health Organization functional class (WHO-FC: a way to classify how limited you are during physical activity)

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.

RATIONALE

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

REFERENCES

- Revatio [Prescribing Information]. New York, NY: Pfizer Inc.; January 2023.
- Liqrev [Prescribing Information]. Farmville, NC: CMP Pharma Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/12/23

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P&T Approval: 04/23