

## PHARMACY POLICY – 5.01.545


## Cialis® (tadalafil) for Benign Prostatic Hyperplasia

Effective Date: Dec. 1, 2017  
Last Revised: Nov. 21, 2017  
Replaces: N/A

RELATED MEDICAL POLICIES:  
5.01.522 Advanced Therapies for Pharmacological Treatment of Pulmonary Arterial Hypertension

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## Introduction

Benign prostatic hyperplasia (BPH) is the medical term for an enlarged prostate. BPH is a noncancerous condition caused by prostate cells that keep multiplying. Over time, the excess prostate tissue puts pressure on the tube that carries urine and semen out of the body. As more pressure is applied, urinary difficulties often develop. These can include a weak or slow stream, a sense that the bladder isn't completely empty, and/or needing to urinate frequently and urgently. Cialis® was originally developed to treat erectile dysfunction (difficulty in achieving and keeping an erection). However, it was discovered that Cialis also addresses symptoms of BPH. This policy describes when Cialis may be approved for BPH. Using Cialis for erectile dysfunction is not covered.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

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Indication	Medical Necessity
<p><b>Treatment for symptoms of benign prostatic hyperplasia (BPH)</b></p>	<p><b>Cialis® (tadalafil) may be considered medically necessary as second line treatment for symptoms of benign prostatic hyperplasia (BPH).</b></p> <p><b>Cialis® (tadalafil) may be considered medically necessary when ALL of the following conditions are met:</b></p> <ul style="list-style-type: none"> <li>• Patient has a diagnosis of benign prostatic hyperplasia (BPH)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Patient has previously failed, had inadequate response to or failed to tolerate a generic alpha blocker (terazosin, tamsulosin, doxazosin, or alfuzosin)</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Patient has previously failed, had inadequate response to or failed to tolerate, Proscar® (finasteride), Avodart® (dutasteride), or Rapaflo® (silodosin)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Prescription is for either 2.5mg or 5mg taken once daily.</li> </ul> <p><b>Note:</b> Cialis® (tadalafil) is also available in 10mg and 20mg tablets for use as needed. These are indicated ONLY for treatment of erectile dysfunction, not BPH.</p>

Indication	Contract Exclusion
<p><b>Erectile dysfunction in patients without BPH</b></p>	<p><b>All other uses of Cialis® (tadalafil) for conditions not outlined in this policy are considered investigational.</b></p>

Indication	Investigational
<p><b>All other indications</b></p>	<p><b>Use of Cialis® (tadalafil) for all other indications is considered investigational.</b></p>

**Note:** Tadalafil is available as Adcirca® in different strengths for the treatment of pulmonary arterial hypertension (PAH). For these patients, refer to the pulmonary arterial hypertension guidelines contained in a separate medical policy. (See [Related Policies](#))



## Coding

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N/A

## Related Information

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### Benefit Application

This policy applies to all lines of business. Language pertaining specifically to contractual exclusion of tadalafil is applicable only to benefits that exclude coverage for treatment of erectile dysfunction.

This policy is managed through the Pharmacy benefit.

## Evidence Review

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### Description

Benign prostatic hyperplasia (BPH) is a condition characterized by epithelial and stromal cell proliferation (enlargement) of the prostate gland. BPH and BPH-related lower urinary tract symptoms (LUTS) are age-dependent, with BPH being one of the top 10 most commonly diagnosed conditions in men over 50 years of age. The estimated prevalence of LUTS secondary to BPH in Caucasian Americans between the ages of 50 and 79 in 2000 was 42%. In a European cross sectional study of men >40 years of age attending urology clinics, the prevalence of LUTS secondary to BPH was 56% and erectile dysfunction was 40%. These conditions are also frequently comorbid in the same men. In BPH, as the prostate gland enlarges it may constrict the urethra and/or the bladder wall may thicken and become irritable resulting in lower urinary tract symptoms such as diminished urine stream, intermittency, straining, polyuria, nocturia, urinary urgency, and inability to empty the bladder.

Three classes of drugs are currently recommended by the AUA for the treatment of BPH: alpha adrenergic antagonists, 5-alpha reductase inhibitors, and anticholinergics. The approval of



tadalafil for BPH occurred after the latest AUA management update; consequently its use for BPH is not addressed. The mechanism of action of alpha adrenergic antagonists is blockade of alpha-1 receptors in the prostate, bladder, and urethra which relaxes smooth muscle in these tissues and improves urine flow and symptoms associated with BPH. It is important to note that drugs in this class do not reduce prostate size. 5-Alpha reductase inhibitors interfere with testosterone's stimulatory effect on prostate enlargement and therefore do reduce prostate size.

Alpha-1 adrenergic antagonists are generally considered a preferred first-line treatment option for patients with moderate to severe LUTS secondary to BPH. However, prazosin and phenoxybenzamine are not recommended due to a lack of evidence of effectiveness. Use of 5-alpha reductase inhibitors is recommended for patients with moderate to severe LUTS and demonstrated increased prostatic volume, prostate specific antigen (as a proxy for volume), and/or prostatic enlargement on digital rectal exam. These agents are not recommended for the treatment of LUTS in men without prostatic enlargement. Combination therapy with an alpha adrenergic antagonist and a 5-alpha reductase inhibitor has been shown to provide greater symptom relief and reduction in disease progression (prostate enlargement) compared with an agent from either class alone.

## Rationale

The clinical efficacy of tadalafil 5 mg once daily for lower urinary tract symptoms (LUTS) suggestive of benign prostatic hyperplasia (BPH) was primarily established in 3 similarly designed multinational, 12-week, randomized, double-blind, placebo-controlled trials. Two of these studies were conducted in men with LUTS suggestive of BPH (Porst, 2011 and Roehrborn, 2008) and one was specific to men with comorbid BPH and erectile dysfunction (Egerdie, 2011). The primary efficacy endpoint in all 3 trials was change from baseline in total International Prostate Symptom Score (IPSS). The IPSS assesses severity of the spectrum of symptoms associated with BPH. The comorbid ED study had a co-primary endpoint that was change from baseline in the erectile function domain score of International Index of Erectile Function (IIEF-EF). All 3 trials consistently showed a statistically and clinically significant improvement in these surrogate outcomes after 12-weeks. While these studies were not specifically designed to evaluate the following endpoints, nocturia and objective urodynamic measures (peak urinary flow and postvoid residual volume) were consistently not improved.

A 1-year, open-label, safety extension of the registrational Roehrborn (2008) study suggests efficacy for LUTS secondary to BPH is maintained longer-term (Donatucci, 2011). Two other preliminary RCTs also consistently support the short-term (12-week) efficacy of tadalafil 5 mg once daily for LUTS secondary to BPH with or without comorbid ED.



Results from one unpublished, multinational, 12-week, randomized, double-blind, double dummy, placebo-controlled trial with a parallel tamsulosin (FLOMAX) 0.4 mg once daily arm were recently posted on clinicaltrials.gov (NCT00970632). While this study was not designed to compare the two active drugs, tadalafil 5 mg once daily appeared to provide similar improvements to that of tamsulosin (FLOMAX) 8 in men with LUTS suggestive of BPH. As might be expected, tadalafil appeared superior to the alpha-blocker for treatment of comorbid erectile dysfunction.

One prospective, open-label, uncontrolled study was identified on literature search that examined the efficacy and safety of add-on tadalafil at the approved 5 mg daily dose combined with an alpha-blocker (tamsulosin [FLOMAX] 0.2 mg or alfuzosin [UROXATRAL] 10 mg) for 12-weeks in 158 Korean men with concurrent LUTS-BPH and ED. Total IPSS and IIEF-5 were significantly ( $p < 0.001$ ) improved with combination therapy, but Qmax and PVR did not, compared to baseline low-dose alpha-blocker monotherapy.

The registrational RCTs show tadalafil 5 mg once daily to be well tolerated for the short-term treatment of LUTS suggestive of BPH with or without comorbid ED. Overall, adverse events were infrequent and the majority (>95%) were mild to moderate in severity. No unexpected adverse events occurred. No clinically significant changes in vitals or electrocardiogram were observed. Rates of myocardial infarction appeared similar to that of placebo in the same population, with the caveat that these trials were of short duration (12 weeks). In short-term (12-week) clinical trials, incidence of a positive orthostatic test was similar in tadalafil-treated and placebo-treated LUTS-BPH patients, about 20%. No priapism was reported.

A long-term (1-year) safety extension in the target population found no new or greater frequency of any adverse events, serious adverse events, or discontinuation for adverse events compared to double-blind short-term (12-week) treatment (Donatucci, 2011).

Two open-label safety extension trials of tadalafil 5 mg once daily in men with ED also showed the drug to be well tolerated for up to 2 years. No unexpected adverse events were observed. No deaths or serious adverse events, cardiovascular or otherwise, were attributed to study drug.

No sudden hearing or vision losses (non-arteritic anterior ischemic optic neuropathy [NAION]) were reported in short- or long-term clinical trials for LUTS secondary to BPH.

In the unpublished, multinational, 12-week, randomized, double-blind, double dummy, placebo-controlled trial with the parallel tamsulosin 0.4 mg once daily arm (NCT00970632), incidence of adverse events, serious adverse events, and discontinuation for adverse events appeared similar between tadalafil (CIALIS) 5 mg, tamsulosin (FLOMAX) 0.4 mg, and placebo once daily in men with LUTS-BPH with or without ED.



A prospective, multicenter, randomized, open-label, parallel-group study (Yoshida et al. 2017) compared the efficacy and safety of silodosin versus tadalafil in 192 patients with LUTS-BPH. The primary efficacy endpoint was change in IPSS total symptom score before and after Period 1 treatment (Week 4). Both silodosin and tadalafil demonstrated statistically significant improvement from baseline (Week 0) IPSS total symptom score, with a mean  $\pm$  SD change of  $-10.1 \pm 6.4$  ( $P < 0.0001$ ) and  $-8.0 \pm 6.3$  ( $P < 0.0001$ ), respectively. The difference between silodosin and tadalafil was statistically significant ( $P = 0.0277$ ). In addition, silodosin demonstrated a significantly greater decrease in symptoms of incomplete emptying, weak stream, and nocturia than tadalafil ( $P = 0.0254$ ,  $P = 0.0067$ , and  $P = 0.0387$ ). Adverse drug reactions occurred more frequently with silodosin (23.4%) than tadalafil (8.4%), but no serious adverse reactions were observed in both arms. Nervous system disorders (i.e., dizziness and headache) and gastrointestinal disorders (i.e. soft feces) were reported in both arms, but orthostatic hypotension (n=2), nasal congestion (n=4), ejaculation disorder (n=6), and retrograde ejaculation (n=5) were only reported in the silodosin arm.

### ***2014 Update***

Updated per literature search 7/1/13 to 10/31/14. No changes required.

### ***2015 Update***

Updated per literature search 11/1/14 to 9/15/15. There was no information which prompted a change in the policy statements. Added Rapaflo as a qualifier to coverage of Cialis along with Proscar and Avodart. Verbiage also updated to call them out separately from the generic alpha blockers.

### ***2016 Update***

A literature search was conducted between 04/01/15 and 12/06/16. No information was found which would prompt a change in the existing policy statements.



## 2017 Update

A literature search was conducted between 07/01/16 and 11/01/17. No information was found which would prompt a change in the existing policy statements.

## References

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## History

Date	Comments
08/12/13	New policy. Add to Prescription Drug section.
12/17/14	Annual Review. Policy updated with literature review. No change in policy statements.
10/13/15	Annual Review. Added Rapaflo as a qualifier to coverage of Cialis along with Proscar and Avodart. Verbiage also updated to call them out separately from the generic alpha blockers. Policy statements unchanged.
01/01/17	Annual Review, approved December 13, 2016. No changes to Policy Criteria.
12/01/17	Annual Review, approved November 21, 2017. No changes to the Policy Criteria. One study was added to the Reference List.

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この通知には重要な情報が含まれています。この通知には、Premera Blue Cross の申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性がある重要な日付をご確認ください。健康保険や有料サポートを維持するには、特定の期日までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

**한국어 (Korean):**

본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

**ລາວ (Lao):**

ແຈ້ງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈຳເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວີ້ ຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

**ភាសាខ្មែរ (Khmer):**

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការផ្ទៃក្នុងដូចជា ឆ្លើយតបនឹងស្នើសុំឱ្យអ្នកកាមរយ: Premera Blue Cross ។ ប្រសិនបើមានការសង្ស័យអំពីព័ត៌មាននេះ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

**ਪੰਜਾਬੀ (Punjabi):**

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਕੱਠ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਰਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

**فارسی (Farsi):**

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

**Polskie (Polish):**

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

**Português (Portuguese):**

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

**Română (Romanian):**

Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

**Русский (Russian):**

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

**Fa'asamoa (Samoan):**

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

**Español (Spanish):**

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

**Tagalog (Tagalog):**

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

**ไทย (Thai):**

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

**Український (Ukrainian):**

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

**Tiếng Việt (Vietnamese):**

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).