Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation

Introduction

The heart is divided into two upper and two lower chambers. Atrial fibrillation, also called a-fib, occurs when the upper chambers of the heart beat irregularly and often rapidly, and as a result blood isn’t pumped out of them the way that it should. This causes blood to tend to pool in the two upper chambers. The pooling blood increases the risk of blood clots forming in an area of the heart called the left atrial appendage. If the blood clot comes loose it may travel to the brain and cause a stroke. Blood thinners are the usual method of preventing blood clots in people with a-fib. If taking a blood thinner poses too much risk or a person can’t tolerate this medication, placing a device in the heart is a different way of preventing stroke. This device seals off the left atrial appendage. Should a clot develop there, the device blocks it clot from entering the bloodstream. This policy describes when a left atrial appendage closure device is considered medically necessary.

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Percutaneous left atrial appendage closure device (eg, the Watchman) | The use of the FDA-approved Watchman device for percutaneous left atrial appendage closure may be considered medically necessary under the following conditions:  
  - There is a diagnosis of atrial fibrillation  
  AND  
  - There is an increased risk of stroke and systemic embolism based on either:  
    o CHADS2 - is greater than or equal to 2 (Congestive heart failure, Hypertension, Age > 75, Diabetes, Stroke/TIA/thromboembolism)  
    OR  
    o CHA2DS2-VASc – is greater than or equal to 3 (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/TIA/thromboembolism, Vascular disease, Sex category – 0 for male; 1 for female)  
  AND  
  - Patient is unable to use systemic anticoagulation therapy based on a high risk of complications-HAS- Bled risk of 3 or more (see Table 1 below)  

The use of a device with FDA-approval for percutaneous left atrial appendage closure (eg, the Watchman) for stroke prevention in patients who do not meet the above criteria is considered investigational. |

<table>
<thead>
<tr>
<th>Device</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other percutaneous left atrial appendage closure devices</td>
<td>The use of other percutaneous left atrial appendage closure devices, including but not limited to the Lariat, PLAATO, and Amplatzer devices, for stroke prevention in patients with atrial fibrillation is considered investigational.</td>
</tr>
</tbody>
</table>
Table 1: Clinical Components of the HAS-BLED Bleeding Risk Score

<table>
<thead>
<tr>
<th>Letter</th>
<th>Clinical Characteristic</th>
<th>Points Awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>H</td>
<td>Hypertension</td>
<td>1</td>
</tr>
<tr>
<td>A</td>
<td>Abnormal renal and liver function (1 point each)</td>
<td>1 or 2</td>
</tr>
<tr>
<td>S</td>
<td>Stroke</td>
<td>1</td>
</tr>
<tr>
<td>B</td>
<td>Bleeding</td>
<td>1</td>
</tr>
<tr>
<td>L</td>
<td>Labile INRs</td>
<td>1</td>
</tr>
<tr>
<td>E</td>
<td>Elderly (&gt;65)</td>
<td>1</td>
</tr>
<tr>
<td>D</td>
<td>Drugs or alcohol (1 point each)</td>
<td>1 or 2</td>
</tr>
</tbody>
</table>

INR: international normalized ratio.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>33340</td>
<td>Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation (new code effective 1/1/17)</td>
</tr>
<tr>
<td>33999</td>
<td>Unlisted procedure, cardiac surgery</td>
</tr>
<tr>
<td>93799</td>
<td>Unlisted cardiovascular service or procedure</td>
</tr>
<tr>
<td>0281T</td>
<td>Percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation (code terminated 1/1/17, replaced with 33340)</td>
</tr>
</tbody>
</table>

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The balance of risks and benefits associated with implantation of the Watchman device for stroke prevention, as an alternative to systemic anticoagulation with warfarin, must be made on an individual basis.

Bleeding is the primary risk associated with systemic anticoagulation. A number of risk scores have been developed to estimate the risk of significant bleeding in patients treated with systemic anticoagulation. An example is the HAS-BLED score, which has been validated to assess the annual risk of significant bleeding in patients with AF treated with warfarin (Pisters et al., 2010). The score ranges from 0 to 9, based on a number of clinical characteristics (see Table 1). Risk of major bleeding in patients with scores of 3, 4, and 5 has been reported at 3.74 per 100 patient-years, 8.70 per 100 patient-years, and 12.5 per 100 patient-years, respectively. Scores of 3 or greater are considered to be associated with a high risk of bleeding, potentially signaling the need for closer monitoring of patients for adverse risks, closer monitoring of international normalized ratio, or differential dose selections of oral anticoagulants or aspirin (January et al, 2014).

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**Evidence Review**

**Description**

Stroke prevention in atrial fibrillation (AF) is an important goal of treatment. Treatment with anticoagulant medications is the most common approach to stroke prevention. Most embolic strokes originate from the left atrial appendage; therefore, occlusion of the left atrial appendage may offer a nonpharmacologic alternative to anticoagulant medications for the prevention of stroke in patients with AF. Multiple percutaneously deployed devices are being investigated for left atrial appendage closure. There is one left atrial appendage (LAA) occlusion device (the Watchman™ device) with approval from the U.S. Food and Drug Administration (FDA) for stroke prevention in patients with AF.

**Background**

**Stroke**

Stroke is the most serious complication of atrial fibrillation (AF). The estimated incidence of stroke in nontreated patients with AF is 5% per year. Stroke associated with AF is primarily
embolic in nature, tends to be more severe than the typical ischemic stroke, and causes higher rates of mortality and disability. As a result, stroke prevention is one of the main goals of AF treatment.

Stroke in AF occurs primarily as a result of thromboembolism from the left atrium. The lack of atrial contractions in AF leads to blood stasis in the left atrium, and this low flow state increases the risk for thrombosis. The area of the left atrium with the lowest blood flow in AF, and, therefore, the highest risk of thrombosis, is the left atrial appendage (LAA). It has been estimated that 90% of left atrial thrombi occur in the LAA.

Treatment

**Anticoagulation**

The main treatment for stroke prevention in AF is anticoagulation, which has proven efficacy. The risk for stroke among patients with AF is stratified on the basis of several factors. A commonly used score, the CHADS2 score, assigns 1 point each for the presence of heart failure, hypertension, age 75 years or older, diabetes, or prior stroke or transient ischemic attack. The CHADS2-VASc score includes sex, more age categories, and the presence of vascular disease, in addition to the risk factors used in the CHADS2 score. Warfarin is the predominant anticoagulation agent in clinical use. A number of newer anticoagulant medications, including dabigatran, rivaroxaban, and apixaban, have recently received U.S. Food and Drug Administration (FDA) approval for stroke prevention in nonvalvular AF and have demonstrated noninferiority to warfarin in clinical trials. While anticoagulation is effective for stroke prevention, there is an increased risk of bleeding. Also, warfarin requires frequent monitoring and adjustments, as well as lifestyle changes. Dabigatran does not require monitoring. However, unlike warfarin, the antithrombotic effects of dabigatran are not reversible with any currently available hemostatic drugs. Guidelines from the American College of Chest Physicians recommend the use of oral anticoagulation for patients with AF who are at high risk of stroke (ie, CHADS2 score ≥ 2), with more individualized choice of antithrombotic therapy in patients with lower stroke risk.¹

Bleeding is the primary risk associated with systemic anticoagulation. A number of risk scores have been developed to estimate the risk of significant bleeding in patients treated with systemic anticoagulation. An example is the HAS-BLED score, which has been validated to assess the annual risk of significant bleeding in patients with AF treated with warfarin.² The score ranges from 0 to 9, based on a number of clinical characteristics, including the presence of hypertension, renal and liver function, history of stroke, bleeding, labile international normalized
ratios (INRs), age, and drug/alcohol use. Scores of 3 or greater are considered to be associated with high risk of bleeding, potentially signaling the need for closer monitoring of the patient for adverse risks, closer monitoring of INRs, or differential dose selections of oral anticoagulants or aspirin.³

**Surgery**

Surgical removal, or exclusion, of the LAA is often performed in patients with AF who are undergoing open heart surgery for other reasons. Percutaneous LAA closure devices have been developed as a nonpharmacologic alternative to anticoagulation for stroke prevention in AF. The devices may prevent stroke by occluding the LAA, thus preventing thrombus formation.

Several versions of LAA occlusion devices have been developed. The Watchman Left Atrial Appendage System (Boston Scientific, Marlborough, MA) is a self-expanding nickel titanium device. It has a polyester covering and fixation barbs for attachment to the endocardium. Implantation is performed percutaneously through a catheter delivery system, using venous access and transseptal puncture to enter the left atrium. Following implantation, patients receive anticoagulation with warfarin or alternative agents for approximately 1 to 2 months. After this period, patients are maintained on antiplatelet agents (ie, aspirin and/or clopidogrel) indefinitely. The Lariat Loop Applicator is a suture delivery device that is intended to close a variety of surgical wounds in addition to LAAC. The Cardioblate® closure device (Medtronic) is currently being tested in clinical studies. The Amplatzer cardiac plug (St. Jude Medical, Minneapolis, MN), is FDA-approved for closure of atrial septal defects but not LAAC device. A second-generation device, the Amplatzer Amulet, has been developed to seal off the LAA. The Percutaneous LAA Transcatheter Occlusion device (ev3, Plymouth, MN) has also been evaluated in research studies but has not received FDA approval. The Occlutech® (Occlutech, Sweden) Left Atrial Appendage Occluder has received a CE mark for coverage in Europe.

**Summary of Evidence**

For individuals who have atrial fibrillation (AF) who are at increased risk for embolic stroke who receive the Watchman percutaneous left atrial appendage closure (LAAC) device, the evidence includes 2 randomized controlled trials (RCTs) and meta-analyses of these trials. Relevant outcomes are overall survival, morbidity events, and treatment-related morbidity. The most relevant evidence comes from 2 industry-sponsored RCTs that compared the Watchman device with anticoagulation. One trial reported noninferiority on a composite outcome of stroke, cardiovascular/unexplained death, or systemic embolism after 2 years of follow-up, with
continued benefits with the Watchman device after 4 years of follow-up. The second trial did not demonstrate noninferiority for the same composite outcome, but did demonstrate noninferiority of the Watchman device to warfarin for late ischemic stroke and systemic embolization. Patient-level meta-analyses of the 2 trials reported that the Watchman device is noninferior to warfarin on the composite outcome of stroke, systemic embolism, and cardiovascular death. Also, the Watchman was associated with a higher periprocedural risk of bleeding and ischemic stroke but a lower risk of hemorrhagic stroke over the long term. The published evidence indicates that the Watchman device is efficacious in preventing stroke for patients with AF who are at increased risk for embolic stroke. When it is determined on an individualized basis that the long-term risk of systemic anticoagulation exceeds the procedural risk of device implantation, the net health outcome will be improved. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have AF who are at increased risk for embolic stroke who receive a percutaneous LAAC device other than the Watchman device (eg, the Lariat, Amplatzer, and PLAATO devices), the evidence includes uncontrolled case series. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity. Case series of these devices have reported high procedural success, but also numerous complications. In addition, these devices do not have the U.S. Food and Drug Administration approval for LAAC. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this policy are listed in Table 2.

### Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT02039167</td>
<td>WATCH Bleeding Episodes After Left Atrial Appendage Occlusion Versus Usual Care in Patients With Atrial Fibrillation and Severe to eNd-stage Chronic Kidney Disease (WatchAFIB in CKD)</td>
<td>300</td>
<td>Jun 2017</td>
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<tr>
<td>NCT01182441</td>
<td>Evaluation of the Watchman LAA closure device in patients with atrial fibrillation versus long term warfarin</td>
<td>475</td>
<td>Aug 2017</td>
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<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------------------------------------------------------------------</td>
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<tr>
<td>NCT02426944</td>
<td>Left Atrial Appendage Closure vs Novel Anticoagulation Agents in Atrial Fibrillation</td>
<td>400</td>
<td>May 2020</td>
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<tr>
<td>NCT02879448</td>
<td>AMPLATZER™ Amulet™ Left Atrial Appendage Occluder Randomized Controlled Trial</td>
<td>1600</td>
<td>Dec 2023</td>
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<tr>
<td>NCT01363895</td>
<td>Interventional Strategies in Treatment of Atrial Fibrillation: Percutaneous Closure of the Left Atrial Appendage Versus Catheter Ablation</td>
<td>120</td>
<td>Nov 2013</td>
</tr>
<tr>
<td>NCT01628068</td>
<td>Efficacy of Left Atrial Appendage Closure After Gastrointestinal Bleeding</td>
<td>120</td>
<td>Jul 2014</td>
</tr>
<tr>
<td>NCT01118299</td>
<td>AMPLATZER Cardiac Plug Clinical Trial</td>
<td>3000</td>
<td>Not approved/cleared</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input

In response to requests, input was received from 1 physician specialty society (2 responses) and 4 academic medical centers, one of which provided 4 responses, for a total of 9 responses, while this policy was under review in 2015. The input generally supported the use of an FDA-approved LAA closure device for patients with an increased risk of stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc score and systemic anticoagulation therapy is recommended, but the long-term risks of systemic anticoagulation outweigh the risks of the device implantation.
Practice Guidelines and Position Statements

American College of Cardiology, Heart Rhythm Society, et al.

In 2015, the American College of Cardiology (ACC), Heart Rhythm Society (HRS), and Society for Cardiovascular Angiography and Interventions published an overview of the integration of percutaneous left atrial appendage closure (LAAC) devices into the clinical practice for patients with atrial fibrillation (AF). The overview provided general guidelines for facility and operator requirements, including the presence of a multidisciplinary heart team, for centers performing percutaneous LAAC. It did not provide specific recommendations on indications and patient populations appropriate for percutaneous LAAC.

American College of Cardiology, American Heart Association, et al.

In 2014, ACC, American Heart Association, and HRS issued guidelines on the management of patients with AF. The guidelines recommended that surgical excision of the left atrial appendage (LAA) be considered in patients undergoing cardiac surgery (class IIB recommendation; level of evidence: C), but made no specific recommendations on percutaneous LAAC.

European Society of Cardiology et al.

In 2016, the European Society of Cardiology (ESC) and the European Society for Cardiothoracic Surgery (EACTS) issued guidelines on the management of AF. The guidelines included the following recommendations on occlusion of the LAA in AF (see Table 3).

Table 3. Guidelines on LAA Occlusion or Exclusion

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“After surgical occlusion or exclusion of the LAA, it is recommended to continue anticoagulation in at-risk patients with AF for stroke prevention”</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>“LAA occlusion may be considered for stroke prevention in patients with AF and contraindications for long-term anticoagulant treatment (eg, those with a previous life-threatening bleed without a reversible”</td>
<td>IIb</td>
<td>B</td>
</tr>
</tbody>
</table>
Medicare National Coverage

As of 2016, the Centers for Medicare and Medicaid Services has a national coverage determination (NCD) under coverage with evidence development for percutaneous LAAC in AF, as follows\(^5\).

LAAC devices are covered when the device has received Food and Drug Administration (FDA) Premarket Approval (PMA) for that device’s FDA-approved indication and meet all of the conditions specified below:

The patient must have:

- A CHADS2 score \( \geq 2 \) (Congestive heart failure, Hypertension, Age > 75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA2DS2-VASc score \( \geq 3 \) (Congestive heart failure, Hypertension, Age \( \geq 65 \), Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category)

- A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF [nonvalvular atrial fibrillation] prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record

- A suitability for short-term warfarin but deemed unable to take long-term oral anticoagulation following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants. The patient (preoperatively and postoperatively) is under the care of a cohesive, multidisciplinary team (MDT) of medical professionals. The procedure must be furnished in a hospital with an established structural heart disease (SHD) and/or electrophysiology (EP) program

The procedure must be performed by an interventional cardiologist(s), electrophysiologist(s), or cardiovascular surgeon (s) that meets the following criteria:

- Has received training prescribed by the manufacturer on the safe and effective use of the device prior to performing LAAC; and,
• Has performed ≥ 25 interventional cardiac procedures that involve transseptal puncture through an intact septum; and,

• Continues to perform ≥ 25 interventional cardiac procedures that involve transseptal puncture through an intact septum, of which at least 12 are LAAC, over a 2-year period.

Patients must be enrolled in approved registries that track outcomes for procedures and devices.

**Regulatory Status**

In March 2015, the Watchman™ Left Atrial Appendage Closure Technology (Boston Scientific, Marlborough, MA) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process on the basis of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients with Atrial Fibrillation (PROTECT-AF) randomized controlled trial. This device is indicated to reduce the risk of thromboembolism from the left atrial appendage (LAA) in patients with nonvalvular atrial fibrillation who:

• Are at increased risk for stroke and systemic embolism based on CHADS₂ or CHA₃DS₂-VASc scores and are recommended for anticoagulation therapy;

• Are deemed by their physicians to be suitable for warfarin; and

• Have an appropriate rationale to seek a nonpharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

FDA product code: NGV.

Two other devices have been studied for LAA occlusion, but are not approved in the United States for percutaneous closure of the LAA. In 2006, the Lariat® Loop Applicator device (SentreHEART, Redwood City, CA), a suture delivery system, was cleared for marketing by FDA through the 510(k) process. The intended use is to facilitate suture placement and knot tying in surgical applications where soft tissues are being approximated or ligated with a pretied polyester suture. The Amplatzer Amulet® device (St. Jude Medical, Plymouth, MN) has a CE approval in Europe for LAA closure, but is not currently approved in the United States for any indication.

**References**


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/13/11</td>
<td>Add to Cardiology Section - New medical policy created with literature search; procedure considered investigational.</td>
</tr>
<tr>
<td>12/29/11</td>
<td>Code 0281T added.</td>
</tr>
<tr>
<td>05/22/12</td>
<td>Replace policy. Policy updated with literature review, references 2-4, 6-9, 11, 12 added. Policy title and policy statements revised to include percutaneous – no other change to policy statement.</td>
</tr>
<tr>
<td>09/17/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>05/28/13</td>
<td>Replace policy. Policy updated with literature review through January 2013, references 2, 12-20 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>12/08/15</td>
<td>Annual Review. Policy updated with literature review through May 29, 2015; references 2-3, 6, 9, 12, 21, 33, and 43 added; clinical input reviewed. An FDA-approved left atrial appendage closure device is considered medically necessary with conditions.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Coding update, added new code 33340 effective 1/1/17.</td>
</tr>
</tbody>
</table>

**Disclaimer**: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and
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**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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  • Information written in other languages

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Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://oocrportal.hhs.gov/oocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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Call 800-722-1471 (TTY: 800-842-5357).

Oromo (Ouomo):
 предусوبت галлакын унтараа, галлакын мадаах дарр пахахаан нутабнань моу команда тухоо ол аслмоо пахахаан нутабнань моу команда галлакын унтараа.

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