Letter of Medical Necessity Template

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This is being provided solely for informational purposes and for your independent consideration and review. You should make any and all changes that you believe are appropriate, or disregard these suggestions in their entirety. Arthrex makes no assurances that the use of this letter will guarantee coverage or reimbursement of any item or service. The provider of services has the sole responsibility to determine medical necessity and to submit appropriate codes and charges for care provided in accordance with the particular payor(s)' requirements.

<Date>

<Contact name>
<Title>
<Insurance company name>
<Payor address>

RE: Coverage and Reimbursement Request for ArthroFLEX® for the treatment of a rotator cuff repair
<Patient's name>
<Patient's date of birth>
<Patient's insurance policy information>

Dear <Contact name>:

I am writing to request coverage benefits and reimbursement for <insert patient's first and last name>'s treatment for <injury>. I have evaluated and counseled this patient on various treatment options for their injury and find them a viable candidate for use of ArthroFlex dermal allograft during the surgical procedure. ArthroFlex is coded as the following:

HCPCS Code: Q4125
Long Descriptor: ArthroFlex, per square centimeter
Short Descriptor: ArthroFlex

Mr./Ms. <insert patient's last name> suffers from <describe injury>. A copy of their most recent medical record is enclosed for your review. I believe my patient is an appropriate candidate for repair augmentation with ArthroFlex because:
<procedure name> is a <briefly describe procedure> for the treatment of <diagnosis>. The history of this patient's condition is as follows.

Insert paragraph(s) regarding patient's pertinent medical history information to include:

- Duration of related symptoms
- Prior failed conservative treatments
- Impact on patient's quality of life
- Surgical risk factors such as age, obesity, or other health issues
- Anticipated outcome without treatment and medical benefit of desired treatment based on clinical points supported in the literature

Please refer to Appendix A for peer-reviewed literature in support of ArthroFlex. Additionally, the published literature has identified six prognostic factors that are associated with rotator cuff healing. These six factors have a scoring system called the Rotator Cuff Healing Index (RoHI) that, when totaled,

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can predict the odds of healing. The scores range 0-15 and include grading of the following criteria: age >70, tear size >2.5 cm, tendon retraction, infraspinatus fatty infiltration, bone mineral density ≤-2.5, and high level of work activity. A higher score indicates a higher likelihood of failure. Mr./Ms. <insert patient's last name> has a score of <insert number 0-15>, which represents a statistically higher risk of failure requiring reoperation within two years. A score ≥7 positively predicted failure to heal in 74% of patients. As the score increases, so does the predictability of healing failure. See the breakdown below of the prognostic factors and Mr./Ms. <insert patient's last name> score based on the RoHI as described by Kwon et al (*Am J Sports Med*. 2019;47(1):173-180).

Prognostic factor		Score	Patient score
Patient age (in years)	<70	0	<insert number 0 or 2>
	>70	2	
Tear size	<2.5 cm	0	<insert number 0 or 2>
	>2.5 cm	2	
Tendon retraction	<1 cm	0	<insert number 0, 1, 2, or 4>
	1 to 2 cm	1	
	2 to <3 cm	2	
	≥3 cm	4	
Fatty infiltration of infraspinatus tendon	< grade 2	0	<insert number 0 or 3>
	≥ grade 2	3	
Bone mineral density	>-2.5	0	<insert number 0 or 2>
	≤-2.5	2	
Level of work activity	Low to medium	0	<insert number 0 or 2>
	High	2	
Patient's total score		**Range 0-15**	**<insert number 0-15>**

For this surgical procedure, I plan to use ArthroFlex for the repair and reinforcement of <insert name soft-tissue injury/damage>

In summary, I strongly believe that this surgical procedure utilizing ArthroFlex is medically necessary and warrants coverage to appropriately treat <patient's name>. Their medical history and RoHI score as described above puts this patient at a much higher failure rate that would result in a more difficult reoperation. According to the peer-reviewed literature, the ArthroFlex dermal allograft has been shown to reduce retear rates and provide improved patient-reported outcomes. I am enclosing documentation supporting the medical necessity of this treatment for this patient. I am requesting <payor name> to cover the patient's surgical repair using the ArthroFlex graft. Please contact me at <insert requesting physician's direct telephone number> if you require additional information or would like to discuss the case in greater detail. Thank you for your timely response.

Sincerely,
<Physician name>
<Physician address>

Enclosures <Attach supporting literature>

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Appendix A: Scientific Support for ArthroFLEX® Dermal Allograft

Per the manufacturer LifeNet Health, ArthroFlex is a human dermal allograft procured and processed from donated human tissue using proprietary and patented MatrACELL® technology. The primary function of ArthroFlex dermal allograft is to provide supplemental support for reinforcement of a soft-tissue repair. It is used in various surgical procedures, in both outpatient and inpatient settings, to aid in the treatment of tendon, ligament, and other soft-tissue damage. ArthroFlex allograft will act as a physiological and mechanical barrier that protects the repair site during the early phases of healing. ArthroFlex allograft maintains its natural biomechanical properties and has excellent suture retention, which protects the repair site. ArthroFlex dermal allograft provides a scaffold of native extracellular matrix proteins, creating a natural environment for recipient cellular migration and revascularization and allowing it to rapidly incorporate with the host tissue. Lastly, ArthroFlex allograft is medical device-grade sterile with a sterility assurance level (SAL) of 10^{-6}.

The following peer-reviewed clinical articles demonstrate the safety and efficacy of the ArthroFlex dermal allograft in various sports medicine applications:

Study	Study type and patients	Treatment(s)	Findings reported by authors	Authors' conclusions
Gilot et al *Arthroscopy* 2015 Link	Prospective, nonrandomized, blinded, single-center study of 35 patients with large (3-5 cm) and massive (>5 cm) rotator cuff tears.	Arthroscopic repair with ArthroFlex (n=20) or without augmentation (n=15)	There was a significant difference between the groups in terms of the incidence of retears: 26% (4 retears) in the control group and 10% (2 retears) in the ECM graft group (*P* = .0483). The mean pain level decreased from 6.9 to 4.1 in the control group and from 6.8 to 0.9 in the ECM graft group (*P* = .024). The American Shoulder and Elbow Surgeons score improved from 62.1 to 72.6 in the control group and from 63.8 to 88.9 (*P* = .02) in the treatment group. The mean Short Form 12 scores improved in the two groups, with a statistically significant difference favoring graft augmentation (*P* = .031), and correspondingly, the Western Ontario Rotator Cuff index scores improved in both arms, favoring the treatment group (*P* = .0412).	"The use of ECM for augmentation of arthroscopic repairs of large to massive RCTs reduces the incidence of retears, improves patient outcome scores, and is a viable option during complicated cases in which a significant failure rate is anticipated."
Morris et al *Orthop*	Single-arm prospective study	Repair of massive and recurrent rotator cuff tears	At 24-month follow-up, subjects demonstrated a significant 32.3 (64.4%) mean improvement in	"The assessments and patient satisfaction scores

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Muscular Syst 2018 Link		with ArthroFlex in an older population (n=13)	the Constant-Murley score (*P* = .0001), a significant 32.5 (60.4%) improvement in the ASES score (*P* = .0009), and a significant 31.8 mean in VAS (*P* = .0011) with scores of 82.5, 86.3, and 7.4, respectively. Patient satisfaction was high at 24 months with a reported score of 3.4 and a median of 4.0 (out of 4). There were no complications related to graft use. Only two subjects exhibited radiographic failure with MRIs revealing tears in the native tissue but fully intact graft material. However, these subjects also showed excellent clinical outcome scores.	indicate that significant improvements can be achieved as early as three months with AF-ADM augmentation, despite the severity of these tears and age of the patients. The high success rate was especially notable as the subject group was older patients, who may have greater difficulty healing. The results presented here demonstrate that AF-ADM can be used successfully to treat massive and recurrent rotator cuff tears."
Petri et al *Arthroscopy* 2016 Link	Retrospective review	Open repair of massive rotator cuff tears with ArthroFlex (n=13)	After patch augmentation, there were no complications, no adverse reactions to the patch, and no patients required further surgery. One patient (7.7%) with 4 prior cuff repairs had a documented posterosuperior retear on MRI 2 months after repair. Minimum 2 year outcome scores were available for 12 of 13 (92.3%) shoulders after a mean follow-up period of 2.5 years (range, 2.0 to 4.0 years) The ASES score improved by 21.5 points. Although the pain component of the ASES score and the total ASES score did not improve significantly, the function component of the ASES score improved significantly when compared with their preoperative baselines (*P* < .05). Median patient satisfaction at final follow-up was 9/10 (range, 2 to 10).	"Biologic patch augmentation with human acellular dermal allograft was a safe and effective treatment method for patients with massive rotator cuff retears with deficient posterosuperior rotator cuff tendons in the presence of healthy rotator cuff muscles."
Hammad et al	Retrospective review of data from	Superior capsule reconstruction (SCR) for	Statistically significant improvements were noted in all PROMs at 2-year follow-up. In	"SCR is associated with improvement in patient-reported

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Arthroscopy 2022 Link	Surgical Outcomes Systems database	treatment of massive, irreparable rotator cuff tears (n=350)	total, 240 patients (68.8%) achieved an MCID improvement of >17.5 in ASES score, and 185 patients (52.9%) achieved an MCID of >29.8 improvement in the SANE score. Primary SCRs were associated with a higher MPI in the ASES score and VR-12 physical score compared to revision repairs.	outcomes at short-term follow-up, with 53% to 69% of patients achieving an improvement considered to meet the MCID. Greater improvement is expected when SCR is performed as a primary procedure rather than as a revision procedure for failed rotator cuff repair."
Lacheta et al *Arthroscopy* 2020 Link	Retrospective single-center case-control study of 55 patients with irreparable rotator cuff tears	SCR with ArthroFlex (n=22) or reverse total shoulder arthroplasty (RTSA, n=33)	No significant differences in postoperative outcome scores were detected ($P > .05$) between SCR and RTSA: the mean ASES score was 82.6±15.5 vs 79.3±21.4, mean SANE score was 71.4±24.5 vs 75.4±23.3, mean QuickDASH score was 16.2±16.9 vs 25.3±21.0, and mean SF-12 was 47.7±8.8 vs 46.9±10.4. No significant differences in return-to-sport responses were noted between groups at baseline or postoperatively ($P = .585$, $P = .758$). One SCR was revised at 1.2 years with revision SCR and 1 RTSA had the glenoid component revised day 1 postoperatively for instability.	"SCR using DA results in similar postoperative functional outcomes in a younger patient population when compared to RTSA for the treatment of irreparable posterosuperior rotator cuff tears, without glenohumeral osteoarthritis at short-term follow-up."
Denard et al *Arthroscopy* 2018 Link	Retrospective, multicenter case series with minimum 1-year follow-up	SCR with ArthroFlex for irreparable massive rotator cuff tears (n=59)	Forward flexion improved from 130° preoperative to 158° postoperative, and external rotation improved from 36° to 45°, respectively ($P < .001$). Compared with preoperative values, VAS decreased from 5.8 to 1.7, ASES score improved from 43.6 to 77.5, and SSV score improved from 35.0 to 76.3 ($P < .001$). The AHI was 6.6 mm at baseline and improved to 7.6 mm at 2 weeks postoperatively but decreased to 6.7 mm at final follow-up. 46 cases (74.6%) were considered a success.	"Arthroscopic SCR using dermal allograft provides a successful outcome in approximately 70% of cases in an initial experience. The preliminary results are encouraging in this difficult to manage patient population, but precise indications are important and graft healing is low in our initial experience."

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Pennington et al *Arthroscopy* 2018 Link	Retrospective, single-center case series	SCR for massive irreparable rotator cuff tear (n=86)	Outcomes data revealed improvement in VAS (4.0-1.5), and ASES (52-82) scores at 1 year (*P* = .005). Strength improved significantly (forward flexion/abduction/external rotation of 4.8/4.1/7.7 lb preoperatively to 9.8/9.22/12.3 lb at 1 year) as well as range of motion (forward flexion/abduction of 120°/103° preoperatively to 160°/159° at 1 year) (P = .044/P=.02). At follow-up, 90% of patients were satisfied. A subset of 38 patients had 2-year follow-up. VAS scores in this subset of patients showed significant improvement with a mean of 4.26 preoperatively to 1.24 at 2-year follow-up (*P* < .05) and ASES scores showed significant improvement as well with preoperative mean ASES score of 49.5 and 2-year mean ASES score of 85.3 among the 36 patients without evidence of failure at 2-year follow-up.	"This analysis reveals that arthroscopic SCR with acellular dermal allograft has been successful in decreasing pain and improving function in this patient subset. Radiographic analysis has also shown a consistent and lasting decrease in superior capsular distance and increase in acromiohumeral interval, indicating maintenance of superior capsular stability."
Ely et al *Orthopedics* 2014 Link	Biomechanical study to evaluate gap formation and ultimate tensile failure loads of a rotator cuff tear	Comparison of nonaugmented and augmented rotator cuff repairs using ArthroFlex	The mean ultimate load to failure was 551±113 N for the control and 643±148 N for the augmented group. Mean stiffness in the control group was 53±15 N compared with 63±15 N in the augmented group. Mean displacement to measure gap formation was 2.8±1.3 mm for the control compared with 2.2±1.2 mm in the augmented group.	"This study showed that RTC repair with human dermal allograft ECM scaffold increased the ultimate load to failure by 29% and decreased gap formation by 21% compared with non-augmented controls. The results suggest that the human dermal allograft is able to provide load sharing to protect the repair site during the early healing period."
Van der Meijden et al *Arthroscopy* 2013 Link	Biomechanical study to compare ultimate load to failure of repaired rotator cuff tendons	Comparison of nonaugmented and augmented rotator cuff repairs using ArthroFlex	The intact specimens, double-row (DR) and augmented double-row (aDR) specimens endured more cycles to failure than the single-row (SR) repair	"Augmentation with a collagen patch (aDR) did not influence biomechanical repair qualities in

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	using various techniques		specimens ($P < .05$ for all groups).	this model, but did result in less variability in failure load and more consistency in the mode of failure."
Kwon et al *AJSM* 2019 Link	Case-control study	Primary rotator cuff repair in 603 patients with minimum 12-month imaging of MRI or CT scan to assess repair integrity	The overall healing failure rate was 24%. The following independent risk factors were identified in the multivariate analysis: age >70 years at the time of surgery, size of tear in anteroposterior dimension and retraction, fatty infiltration of infraspinatus exceeding grade 2, low bone mineral density, and high level of work activity. A 15-point scoring system was created and weighted according to multivariate analysis of odds ratios. Patients with ≤4 points had a 6.0% healing failure rate, and those with ≥5 and ≥10 points had 55.2% and 86.2% healing failure rates, respectively.	"A numerical scoring system including significant clinical and radiological factors was designed to predict healing of the rotator cuff after surgical repair. This scoring system helped predict the adequacy of the repair and assist in deciding the appropriate treatment options"
Quigley et al *Arthroscopy* 2022 Link	Decision-tree model to evaluate the cost effectiveness of the use of extracellular matrix (ECM) augment at the time of primary rotator cuff repair	Primary rotator cuff repair with augmentation	"On the basis of our decision tree analysis, total cost for rotator cuff tear without augmentation was $12,763, while the cost increased to $16,039 with ECM augmentation. With graft augmentation that was an improvement in 2.29 QALY (quality-adjusted life years), while there was an improvement of 2.05 without graft augmentation. The ICER (incremental cost effectiveness ratio) of graft augmentation is $14,000/QALY, well below the cost effectiveness cut-off of $50,000/QALY."	"Graft augmentation does come with a significant upfront cost; however, on the basis of our decision-tree analysis, it may represent a cost-effective procedure. There is evidence to potentially consider more routine use in rotator cuff repairs, while being cost effective."