Help Your Patients Refine Their Chin Profile with BELKYRA® (deoxycholic acid) injection

BELKYRA® is indicated for the treatment of moderate to severe convexity or fullness associated with submental fat in adults when the presence of submental fat has a psychological impact for the patient.[1]

belkyra®

Double Chin Is Bothersome To Many Patients

73%

of people said they are bothered by their double chin which is ***as many as those bothered by lines and wrinkles*** around the eyes (73%).*[2]

Submental fullness impacts a range of patients, both adult men and women.[4-6]

Causes of submental fullness[5]

AGING[5]

GENETICS[5]

WEIGHT CHANGE[5]

Recognizing appropriate BELKYRA® candidates in your practice

For adults who are psychologically impacted by moderate to severe submental fat (double chin).[1] BELKYRA® is the only non-surgical injectable first Rx approved treatment for double chin[1]. BELKYRA® destroys fat cells[9] under the chin for an improved chin profile.[1]

Chart adapted from ATX-101 (Deoxycholic Acid Injection) Advisory Committee Briefing Materials, 2015.[7]

*Online survey of respondents, qualified by an interest in cosmetic procedures (N=7,322), who were asked, "How bothered are you by excess fat under the chin/neck?"
†Reported by consumers when asked, "Have you ever looked for information on medical and nonmedical ways to treat this area?"

The Science Behind BELKYRA®

BELKYRA® causes the destruction of fat cells when injected into subcutaneous fat[1,9]

What is BELKYRA®?

- BELKYRA® is a synthetic non-human, non-animal formulation of deoxycholic acid, a naturally-occurring molecule in the body that aids in the breakdown and absorption of dietary fat.[10,11]
- The deoxycholic acid in BELKYRA® is biologically indistinguishable from endogenous deoxycholic acid.[10]

Mechanism of Action

- BELKYRA® causes adipocytolysis, the destruction of fat cells. Once destroyed, those cells cannot store or accumilate fat.[12,13]
- The destruction of adipocytes elicits a tissue response in which macrophages are attracted to the area to eliminate cellular debris and lipids, which are then cleared through natural processes. This is followed by the appearance of fibroblasts and observed thickening of fibrous septa ***suggesting an increase in total collagen*** (i.e., neocollagenesis).[1]

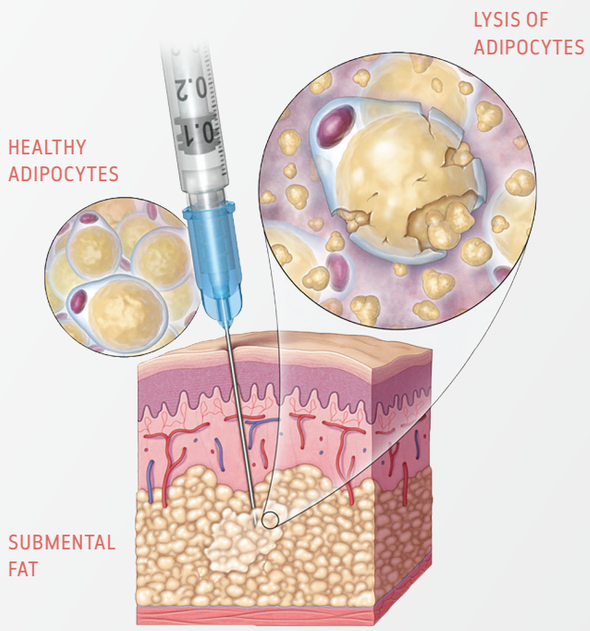


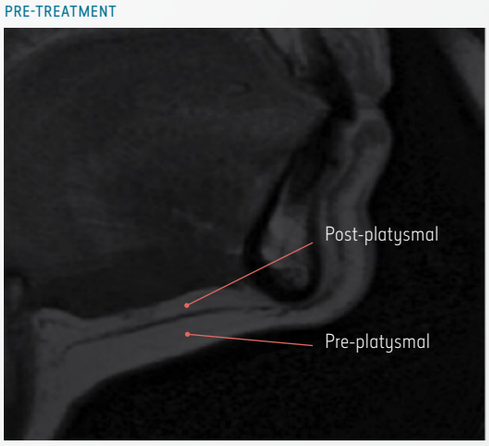
Illustration courtesy of Allergan Inc.

Further treatment is not expected once the aesthetic response is achieved[10]

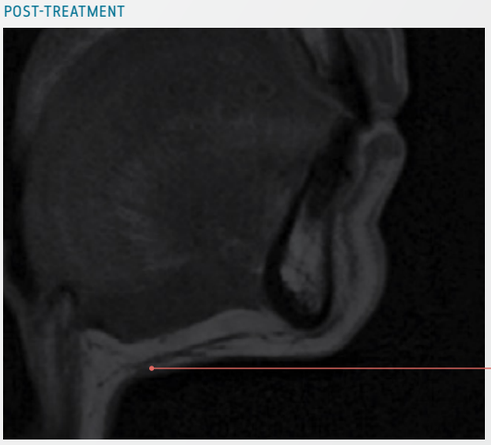
- Submental fat is comprised of the pre-platysmal and post-platysmal fat compartments.[14]
- BELKYRA® is injected into pre-platysmal fat within the treatment area, which is superficial to the platysma muscle.[1,14]

PRE-PLATYSMAL SUBMENTAL FAT REDUCTION WITH BELKYRA®

PRE-TREATMENT



POST-TREATMENT



Visible reduction in pre-platysmal fat under the chin.

Un-retouched MRIs taken before and after 5 treatment sessions with BELKYRA®.
Sex: Female **Age:** 50 **Weight (before):** 129 lbs **Weight (after):** 126 lbs **Number of Treatments:** 5
Individual results may vary.[15]

Images courtesy of Wolters Kluwer Health.[15]

The Results of Treatment with BELKYRA®

A global clinical development program[7]

>20 Clinical Studies

>2,600 Patients Worldwide

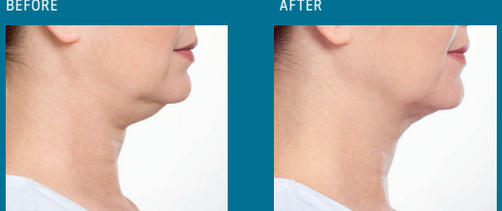
>1,600 Treated with BELKYRA®

Pivotal Clinical Studies

- Four Phase 3 randomized, multi-center, double-blind placebo-controlled trials (2 identical studies conducted in the European Union [EU] and 2 identical trials conducted in North America).[1]
- EU patients received up to 4 treatments with BELKYRA® (n=243) or placebo (n=238), and North American patients received up to 6 treatments with BELKYRA® (n=514) or placebo (n=508), spaced at least one month apart.[1]
- The EU co-primary efficacy assessments were the clinician-reported ratings of submental fullness (CR-SMFRS) and the patient assessment of satisfaction (Subject Self Rating Scale [SSRS]).[1]
- The North American co-primary efficacy assessments were based on ≥2- and ≥1-grade improvements in submental fullness on the CR-SMFRS and the patient-reported (PR-SMFRS) composite ratings.*[1]

≥ 1-GRADE IMPROVEMENT

BEFORE AFTER



Un-retouched photos of paid model taken before and after 4 treatment sessions with BELKYRA®.
Sex: Female **Age:** 48 **Weight (before):** 132.5 lbs **Weight (after):** 131.5 lbs
Number of Treatments: 4 **Total Dose:** 15.6 mL
Individual results may vary.[16]
Images used with permission, Allergan Inc. 2016.

- **78.5% had a ≥1-grade clinician response in pooled North American trials,** compared to 35.3% for placebo patients, based upon validated physician measurements*[1]
- **63.8% had a ≥1-grade patient response in pooled EU trials,** compared to 28.6% for placebo, for subjects who had up to 4 treatment sessions, based upon validated physician measurements[1]

Patient satisfaction

69.1% of North American BELKYRA® patients reported satisfaction (SSRS) with their appearance in association with their face and chin. (*vs.* 30.5% for placebo; $p<0.001$).[1]

65.4% of EU BELKYRA® patients reported satisfaction (SSRS) with their appearance in association with their face and chin (*vs.* 29.0% for placebo; $p<0.001$).†[1]

Improvement in self-perceptions after BELKYRA® treatment

Based on their chin profile, patients reported feeling‡[9]:

- Happier and younger
- Less overweight
- Less embarrassed
- Less bothered
- Less self-conscious

BELKYRA® safety profile

Most common adverse drug reactions reported in ≥10% of BELKYRA® subjects§[1]

Injection site: pain, oedema, swelling, anaesthesia, nodule, haematoma, parasthesia, induration, erythema, pruritus§[1]

- **1.6%** of North American patients (n=8) discontinued study due to adverse reactions, *vs.* 1.0% for placebo (n=5).[17]
- **0.8%** of EU patients (n=2) discontinued study due to adverse reactions, vs. 0.8% for placebo (n=2).**[8]
- Incidence and severity of most adverse events **decreased** with subsequent treatments.[6,10]

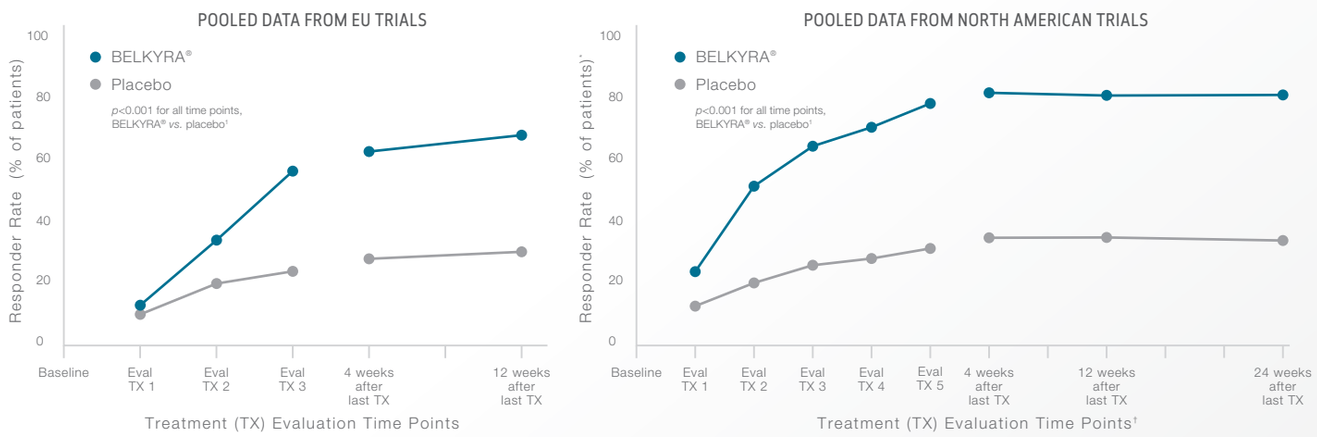
*Composite clinician-reported (CR-SMFRS) ratings of submental fat 12 weeks after final treatment. Defined as a composite response.[1]
†Patient-reported (PR-SSRS) ratings of submental fat 12 weeks after final treatment.[1]
‡Changes from baseline were analyzed by an overall analysis of variance (ANOVA) and pairwise Fisher's Least Significant Difference tests for continuous variables. Intention-to-treat population.[9]
§Adverse reactions that occurred in ≥10% BELKYRA® treated subjects and at greater incidence than placebo.[1]
**Based on safety information from the 2 mg/cm^2 arm of the pooled EU studies.[8]

BELKYRA®
Visible Results

Most BELKYRA® patients have visible results in 2 to 4 treatment sessions[1]

- Number of injections and treatments should be tailored to the individual patient's submental fat distribution and treatment goals[1]

OBSERVED COMPOSITE CLINICIAN SUBMENTAL FULLNESS (CR-SMFRS) 1-GRADE RESPONDER RATES AT EACH STUDY VISIT[1]



- **90%** and **92%** of patients in the EU and North American trials respectively, had no change (68.9% and 70.5%) or an improvement (21.6% and 22.9%) in skin laxity scores 12 weeks after last treatment compared with baseline[1]
- **Up to a maximum of 6 treatments** may be administered no less than 1 month apart[1]
- **Re-treatment is not expected** once the aesthetic result is achieved[10]

Adapted from BELKYRA® Summary of Product Characteristics.[1]

Study Design: four Phase 3 randomized, multi-center, double-blind placebo-controlled trials (2 identical studies conducted in the European Union [EU] and 2 identical trials conducted in North America). EU patients received up to 4 treatments with BELKYRA® (n=243) or placebo (n=238), and North American patients received up to 6 treatments with BELKYRA® (n=514) or placebo (n=508), spaced at least one month apart. North American efficacy assessments were based on ≥2- and ≥1-grade improvements in submental convexity or fullness on the composite clinician-reported ratings of submental fat 24 weeks after final treatment. EU efficacy assessments were based on ≥1-grade improvements in submental convexity or fullness on the clinician-reported ratings of submental fat 12 weeks after final treatment.[1]

BELKYRA® is administered by subcutaneous injection[1]

0.2 mL per injection[1]

≈ 1 cm between injection sites[1]

30 G (or smaller) 0.5-inch needle[18]

- The maximum dose of 10 mL (100 mg, equivalent to 50 injections) should not be exceeded in one treatment session.[1]

Supply and storage information

- BELKYRA® does not need any special storage conditions.
- BELKYRA® should be used immediately once the vial stopper has been penetrated.[1]
- Each vial is for single patient and treatment session use.[1]
- BELKYRA® has a unique hologram on the vial label. If you do not see a hologram, do not use the product.[19]

*Defined as a ≥1-grade composite response, based on observed data.
†Patients were evaluated approximately 4 weeks after each treatment to assess their response.

The First Approved Rx Drug Treatment for Double Chin

Expand your Aesthetic Injectable Portfolio with BELKYRA®

BELKYRA® (deoxycholic acid) injection

- BELKYRA® is an individually-tailored injectable treatment[1] that destroys fat cells under the chin.[9]
- BELKYRA® is documented in more than 20 clinical studies[7].
- Visible results in 2–4 treatments.[1] Surgery is not required.[1,8]
- Long-lasting results[10] and high patient satisfaction.[1]
- Once desired results are achieved, re-treatment is not expected.[10]

BELKYRA® 10 mg/ml injektionsvätska, lösning, deoxicholsyra, övriga dermatologiska medel, ATC-kod: D11AX24, Rx. EF. **Indikation:** Behandling av måttlig till svår utbuktning eller utfyllnad kopplad till submentalt fett (s k dubbelhaka) hos vuxna när förekomsten av submentalt fett har en psykologisk inverkan på patienten. **Kontraindikationer, varningar och försiktighet:** Överkänslighet mot deoxicholsyra eller mot något hjälpämne. Förekomst av infektion vid de planerade injektionsställena.
Patienter bör screenas med avseende på andra orsaker till submental utbuktning eller utfyllnad (t.ex. förstoring av sköldkörteln eller lymfkörteln) före användning av Belkyra. Får endast administreras subkutant, injicera inte närmare än 1 till 1,5 cm från känsliga anatomiska strukturer, får inte injiceras i eller i nära anslutning till ramus marginalis mandibularis, för att undvika risk för motorisk neuropraxi. Försiktighet ska iakttas för att undvika oavsiktlig intradermal eller intramuskulär injektion, undvik injektion i salivkörtlar, tyroideakörtel, lymfknutor och muskulatur, om patienten tidigare har genomgått kirurgisk eller estetiskt behandling i det submentala området, när Belkyra administreras i närvaro av inflammation eller förhårdnader vid det tänkta injektionsstället (-ställena) eller hos patienter med symtom på dysfagi. Texten är baserat på produktresumé med godkännandedatum 2016-10-05. För ytterligare information om produkten samt pris se www.fass.se. Allergan Norden AB, allergansverige@allergan.com.

References: 1. Produktresumé BELKYRA® injektionsvätska lösning 20161005. **2.** American Society for Dermatologic Surgery 2016 Consumer Survey on Cosmetic Dermatologic Procedures (N=7,322). Retrieved 11/18/2016 from: https://www.asds.net/uploadedImages/2016%20Consumer%20Survey%20Infographic.jpg. **3.** BELKYRA® Data on File: INT/0795/2016. **4.** BELKYRA® Data on File: INT/0800/2016. **5.** De Fatta R and Ducic Y. Liposuction of the face and neck. *Operative Techniques in Otolaryngology.* 2007;18:261-266. **6.** Ascher B, *et al.* Efficacy, patient-reported outcomes and safety profile of ATX-101 (deoxycholic acid), an injectable drug for the reduction of unwanted submental fat: results from a phase III, randomized, placebo-controlled study. *JEADV.* 2014; 28:1707-1715. **7.** ATX-101 (DEOXYCHOLIC ACID) Injection Advisory Committee Briefing Materials (available for public release):1-127. Kythera Biopharmaceuticals, Inc.; Feb. 2015. **8.** McDiarmid J, *et al.* Results from a Pooled Analysis of Two European, Randomized, Placebo-controlled, Phase 3 Studies of ATX-101 for the Pharmacologic Reduction of Excess Submental Fat. *Aesth Plast Surg.* 2014; 38:849-860. DOI: 10.1007/s00266-014-0364-9. **9.** Rzany B, *et al.* Reduction of unwanted submental fat with ATX-101. *Br J Dermatol.* 2014; 170:445-453. **10.** Ascher B, Fellmann J and Monheit G. ATX-101 (deoxycholic acid injection) for reduction of submental fat. *Expert Review of Clinical Pharmacology.* 2016; 9(9):1131-1143. DOI: 10.1080/17512433.2016.1215911. **11.** BELKYRA® Bipacksedel 161005. **12.** Rotunda AM. Injectable treatments for adipose tissue: Terminology, Mechanism, and Tissue Interaction. *Lasers in Surgery and Medicine.* 2009; 41:714-720. **13.** Thuangtong R, *et al.* Tissue-selective effects of injected deoxycholate. *Dermatol Surg.* 2010; 36:899-908. **14.** Larson JD, *et al.* Defining the fat compartments in the neck: a cadaver study. *Aesth Surg J.* 2014;34(4):499-506. **15.** Jones DH *et al.* REFINE-1, a Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Trial with ATX-101, an Injectable Drug for Submental Fat Reduction. *Dermatol Surg.* 2015; 0-1-12 DOI: 10:1097/DSS.0000000000000578. **16.** BELKYRA® Data on File: INT/0790/2016. **17.** BELKYRA® Data on File: INT/0791/2016. **18.** Jones DH, *et al.* Proper Technique for Administration of ATX-101 (Deoxycholic Acid Injection): Insights from an Injection Practicum and Roundtable Discussion. *Dermatol Surg.* 2016; 42:S275-S281. DOI: 10.1097/DSS.0000000000000875. **19.** BELKYRA® Data on File: INT/0852/2016.

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