

**KYBELLA**<sup>®</sup>  
(deoxycholic acid) injection 10 mg/mL

# A.C.T. --- NOW

with KYBELLA<sup>®</sup>

Real patient treated with KYBELLA<sup>®</sup>.  
Real results.<sup>1</sup> Results may vary.

Tips and best practices to ASS<sup>ESS</sup>, CONSULT, and TREAT with KYBELLA<sup>®</sup>



## **BOTOX<sup>®</sup> Cosmetic Indications and Important Safety Information**

BOTOX<sup>®</sup> Cosmetic (onabotulinumtoxinA) is a prescription medicine that is injected into muscles and used to temporarily improve the look of moderate to severe forehead lines, crow's feet, frown lines, and vertical bands connecting the neck and jaw in adults (platysma bands).

### **BOTOX<sup>®</sup> Cosmetic Important Safety Information**

Talk to your doctor about BOTOX<sup>®</sup> Cosmetic and whether it's right for you. There are risks with this product—the effects of BOTOX<sup>®</sup> Cosmetic may spread hours to weeks after injection causing serious symptoms. Alert your doctor right away as difficulty swallowing, speaking, breathing, eye problems or muscle weakness can be a sign of a life-threatening condition. If this happens, do not drive a car, operate machinery, or do other dangerous activities. Patients with these conditions before injection are at the highest risk. Swallowing problems may last for several months.

Side effects may include allergic reactions, neck and injection-site pain, fatigue and headache. Don't receive BOTOX<sup>®</sup> Cosmetic if there's a skin infection. Tell your doctor your medical history, muscle or nerve conditions, and medications, including botulinum toxins, as these may increase the risk of serious side effects.

**Please see BOTOX<sup>®</sup> Cosmetic full Product Information, including Boxed Warning and Medication Guide.**

## **INDICATION**

KYBELLA<sup>®</sup> (deoxycholic acid) injection is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.

The safe and effective use of KYBELLA<sup>®</sup> for the treatment of subcutaneous fat outside the submental region has not been established and is not recommended.

## **IMPORTANT SAFETY INFORMATION**

### **CONTRAINDICATIONS**

KYBELLA<sup>®</sup> is contraindicated in the presence of infection at the injection sites.

**Please see additional Important Safety Information throughout and accompanying full Prescribing Information, or visit [https://www.rxabbvie.com/pdf/kybella\\_pi.pdf](https://www.rxabbvie.com/pdf/kybella_pi.pdf)**

# Assess. Consult. Treat.

When it comes to KYBELLA®, we use the acronym A.C.T. (Assess. Consult. Treat.) to summarize the key phases of the patient journey. It is an easy way to introduce KYBELLA® to your patients.

## Assess

It is best practice to ensure that your patients are appropriate candidates for KYBELLA® from the start. There is a series of simple assessments you can do to confirm your patients' severity of submental fullness, individual anatomy, and medical considerations prior to treating with KYBELLA®.

## Consult

Patient education and setting expectations for treatment outcomes are two of the most important components of treatment with KYBELLA®. Be educational and encouraging when speaking to your patients about their submental fullness (double chin)—and the clinical benefits and treatment process of KYBELLA®.

## Treat

Proper injection technique is critical to desired aesthetic outcomes. A working knowledge of the appropriate Treatment Zone and approved dosing can help you tailor treatment to your patients' submental fat distribution and treatment goals.

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS

##### *Marginal Mandibular Nerve Injury*

Cases of marginal mandibular nerve injury, manifested as an asymmetric smile or facial muscle weakness, were reported in 4% of subjects in the clinical trials; all cases resolved spontaneously (range 1-298 days, median 44 days). KYBELLA® should not be injected into or in close proximity to the marginal mandibular branch of the facial nerve.

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# Assess

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### *Dysphagia*

Dysphagia occurred in 2% of subjects in the clinical trials in the setting of administration-site reactions, eg, pain, swelling, and induration of the submental area; all cases of dysphagia resolved spontaneously (range 1-81 days, median 3 days). Avoid use of KYBELLA® in patients with current or prior history of dysphagia as treatment may exacerbate the condition.

**Please see additional Important Safety Information throughout.**

A.C.T.

- First Impression Framework
- Determine submental severity
- Individual anatomy
- Medical considerations

Explore who is right for KYBELLA® using these simple steps to determine candidacy.



# Take a *First Impression*

Use the First Impression Framework to help identify areas of focus for your patients.

## What is the First Impression Framework?

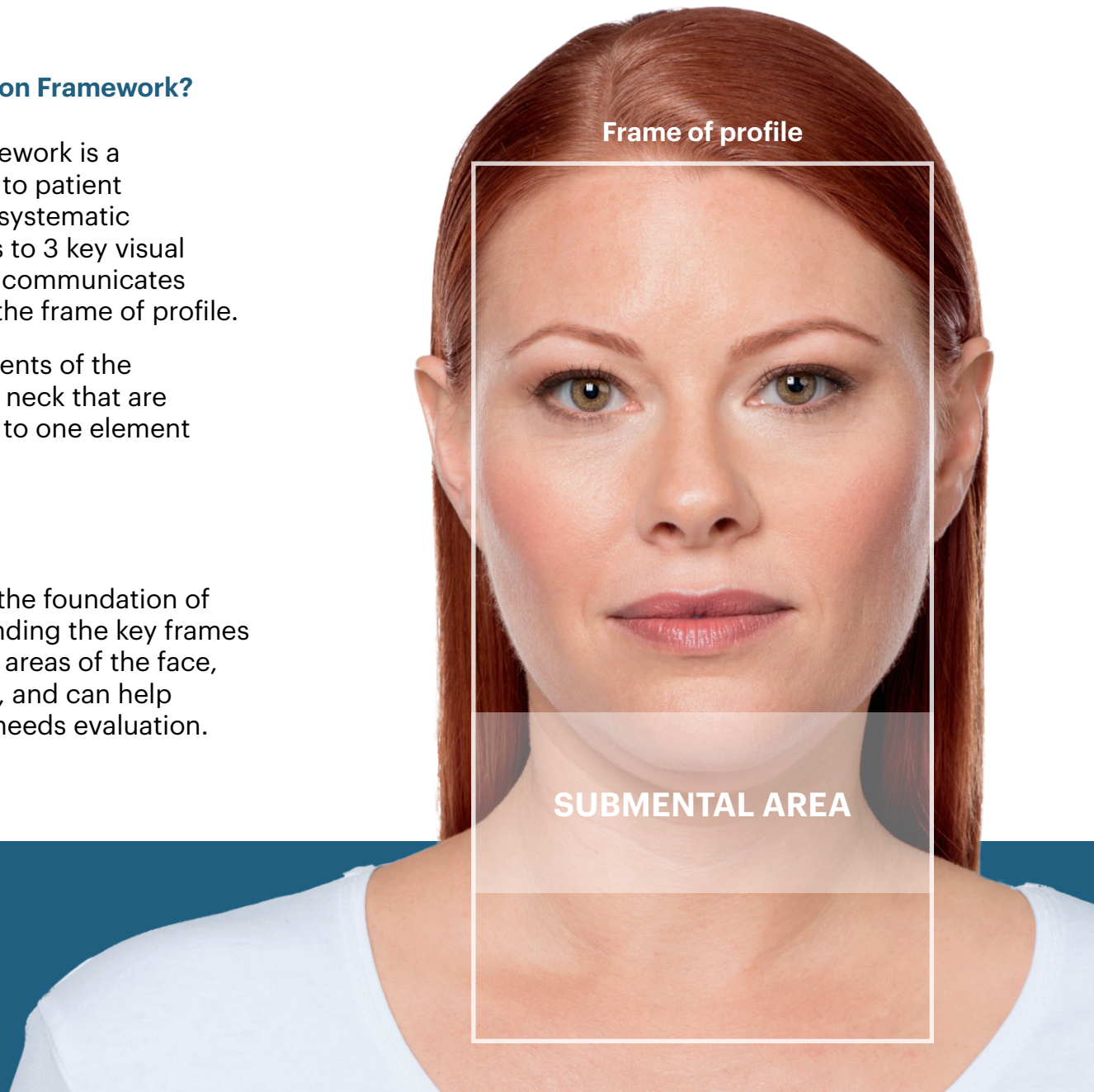
The First Impression Framework is a comprehensive approach to patient assessment. It provides a systematic assessment to bring focus to 3 key visual ways, or frames, a person communicates with the world, including the frame of profile.

Each frame contains elements of the face, submental area, and neck that are interrelated, and changes to one element may impact the others.

## Why is it important?

Anatomical knowledge is the foundation of this framework. Understanding the key frames helps to contextualize the areas of the face, submental area, and neck, and can help complete a full aesthetic needs evaluation.

Be sure to use the First Impression Framework when you **assess patients for moderate to severe submental fullness.**



### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### Injection Site Hematoma/Bruising

In clinical trials, 72% of subjects treated with KYBELLA® experienced hematoma/bruising. KYBELLA® should be used with caution in patients with bleeding abnormalities or who are currently being treated with antiplatelet or anticoagulant therapy as excessive bleeding or bruising in the treatment area may occur.

**Please see additional Important Safety Information throughout.**



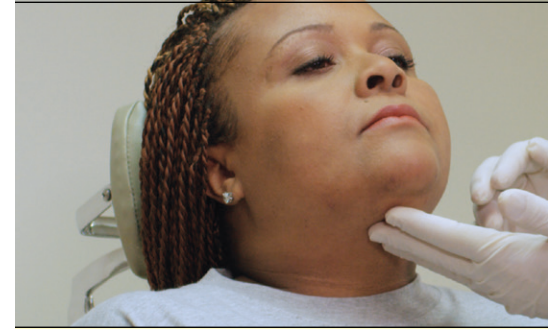
## ANIMATE<sup>1,2</sup>

**Have the patient grimace.** Observe and touch for the presence of palpable preplatysmal fat and key anatomic features, including platysmal banding, submandibular glands, and digastric muscles.



## ROTATE<sup>1</sup>

**Turn the patient's head to the side** so you can assess the severity of their submental fullness and any indication of other potential causes of submental fullness.



## TILT<sup>1</sup>

**Move the patient's chin up and down** to assess for excessive skin laxity and presence of scar tissue, and to evaluate the extent of fat along the lateral margins of the treatment area.

## HELPFUL HINT

Consider a patient's overall facial size, shape, and symmetry. Keep in mind how the patient's gender and ethnicity contribute to their facial features.



## PHOTOS HAVE IMPACT

Patients may or may not be aware of their submental fullness, so show them what they can't see in a mirror. Take photos during your assessment session to discuss later during consultation. See specific photography tips on page 13.

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### Risk of Injecting Into or in Proximity to Vulnerable Anatomic Structures

To avoid the potential of tissue damage, KYBELLA® should not be injected into or in close proximity (1 cm-1.5 cm) to salivary glands, lymph nodes, and muscles. Care should be taken to avoid inadvertent injection directly into an artery or a vein as it can result in vascular injury.

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# Explore Baseline Anatomy With 5 Simple Tests

Screen the patient for other potential causes of submental convexity or fullness while also looking for other conditions that may result in an aesthetically undesirable outcome.<sup>1</sup>



Real patient. Results may vary.

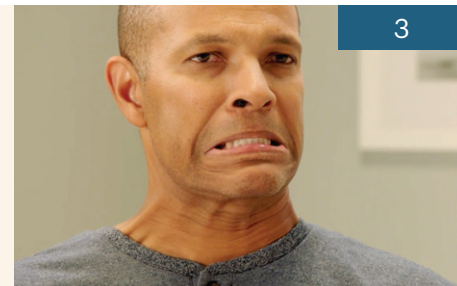
## SKIN QUALITY<sup>2-4</sup>

- Pinch the preplatysmal fat to look for good skin quality (ie, no excessive skin laxity) and palpability



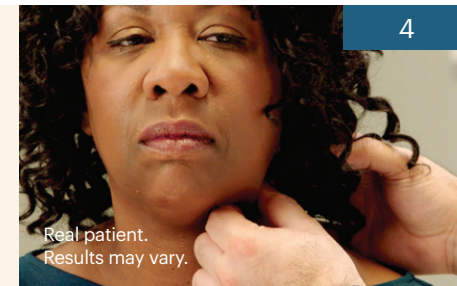
## SKIN LAXITY<sup>4,5</sup>

- Pinch and hold out neck skin. Let the skin go. If it stays without much bounce-back, the patient may have too much skin laxity and would not be an ideal candidate for KYBELLA®



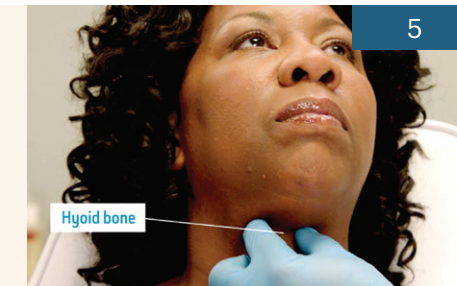
## DIGASTRIC MUSCLE HYPERTROPHY<sup>6,7</sup>

- Ask the patient to stick their tongue to the roof of their mouth while grimacing
- Look for digastric muscle hypertrophy; the technique also pushes postplatysmal fat up to more easily pinch and see preplatysmal fat



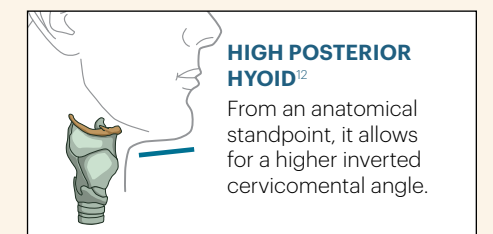
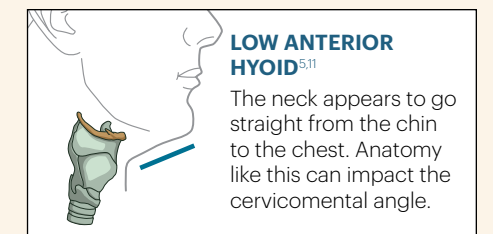
## SUBMANDIBULAR GLANDS<sup>1,2,8</sup>

- Feel for the location of the submandibular glands laterally
- Avoid injecting into these salivary glands. Inject only if the lateral fullness is due to preplatysmal fat



## HYOID BONE<sup>8-10</sup>

- Assess the position of the hyoid bone, as its location can impact the cervicomental angle



### IMPORTANT REMINDER

Healthcare professionals must understand the relevant submental anatomy and associated neuromuscular structures in the area involved and any alterations to the anatomy due to prior surgical or aesthetic procedures.<sup>1</sup>

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### Injection Site Alopecia

Cases of injection site alopecia have been reported with administration of KYBELLA®. Onset and duration may vary among individuals and may persist. Consider withholding subsequent treatments until resolution.

##### Injection Site Ulceration, Necrosis, and Infection

Injections that are too superficial into the dermis may result in skin ulceration and necrosis. Cases of injection site ulceration, necrosis, and infection have been reported with administration of KYBELLA®. Some cases of injection site infection have included cellulitis and abscess requiring antibiotic treatment and incision and drainage. Do not administer KYBELLA® into affected area until complete resolution.

#### ADVERSE REACTIONS

The most commonly reported adverse reactions in the pivotal clinical trials were: injection site edema/swelling, hematoma/bruising, pain, numbness, erythema, and induration.

Please see additional Important Safety Information throughout.

#### INDICATION

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#### IMPORTANT SAFETY INFORMATION

##### CONTRAINDICATIONS

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# Determine *Patient Candidacy*

KYBELLA® is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.<sup>1</sup> Ensuring that your patient is an appropriate candidate for treatment is critical to desired outcomes.

## APPROPRIATE CANDIDATES<sup>1</sup>



- Preplatysmal fat
- Moderate to severe submental fullness
- Minimal skin laxity
- Absence of prominent platysma bands

## POOR CANDIDATES<sup>1,2</sup>



- Extreme submental fullness
- Excessive skin laxity
- Prominent platysma bands
- Scars
- Submandibular glands and digastric muscles

### HELPFUL HINT

If the patient is an appropriate candidate for treatment, move the conversation to discuss the benefits of KYBELLA®. See the next section for details.

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS

##### *Marginal Mandibular Nerve Injury*

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**Please see additional Important Safety Information throughout.**

### IMPORTANT SAFETY CONSIDERATIONS<sup>1</sup>

- Current or prior history of dysphagia
- Treatment with antiplatelet or anticoagulant therapy
- Bleeding abnormalities
- Prior surgical or aesthetic procedures in the submental treatment area

### CONTRAINDICATIONS<sup>1</sup>

- The presence of infection at the injection sites

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# Key Points to Remember



**A.C.T.** (Assess. Consult. Treat.) is an easy way to remember the 3 phases of the KYBELLA® experience.



Use the **First Impression Framework** to assess the severity of submental fullness and baseline anatomy that may impact outcomes.



Remember that there are other safety considerations for candidacy, including prior or current medical conditions or procedures.



The use of photos during assessment can be impactful in discussing submental fullness with patients.

## IMPORTANT SAFETY INFORMATION (continued)

### WARNINGS AND PRECAUTIONS (continued)

#### Injection Site Hematoma/Bruising

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**A.C.T.**

# Consult

- Patient education
- Setting expectations
- Encouraging conversations
- Clinical benefits

## IMPORTANT SAFETY INFORMATION (continued)

### WARNINGS AND PRECAUTIONS (continued)

#### Risk of Injecting Into or in Proximity to Vulnerable Anatomic Structures

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Please see additional Important Safety Information throughout.

Open conversations about KYBELLA® and your patients' desired aesthetic goals using these robust consultation tips.

# Start the *Conversation*

Spend quality time with patients during the consultation. This will provide the time necessary to properly discuss KYBELLA® and learn about your patients' aesthetic goals.



## MAXIMIZE THE PATIENT JOURNEY

Talk with your staff to get their insights on ways to better introduce KYBELLA® to your patients. Have them access a variety of useful training tools on the Allergan Medical Institute online. Ensure that they feel confident speaking about KYBELLA®.



## BRINGING UP KYBELLA®

Use open-ended questions, and listen closely for points you can revisit in subsequent treatment sessions. Probe to understand why a patient finds their double chin bothersome.

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

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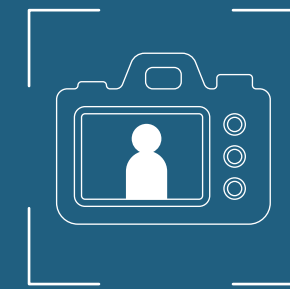
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#### ADVERSE REACTIONS

The most commonly reported adverse reactions in the pivotal clinical trials were: injection site edema/swelling, hematoma/bruising, pain, numbness, erythema, and induration.

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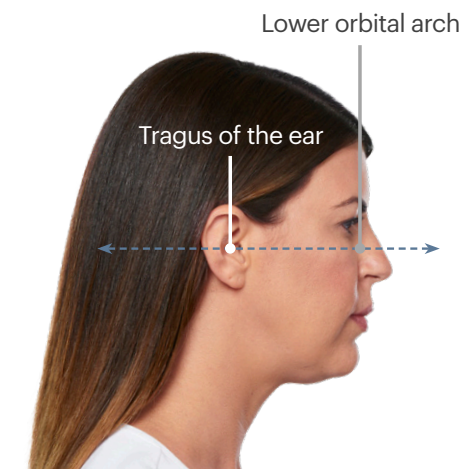


## TAKE QUALITY BEFORE-AND-AFTER PHOTOS

Patients can see their submental profile in photos from angles they may not notice in a mirror. Shoot from multiple angles before every treatment to help track the patient's journey.

## PHOTOS MATTER

Prioritize consistent B&A photography by making sure to align your patient's head position in the same place, every time. Use anatomical landmarks as your guide.

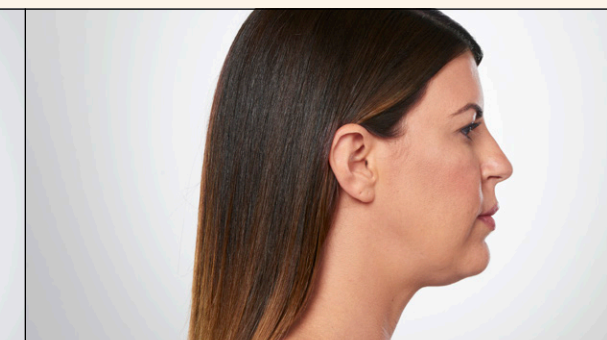


A horizontal plane from the lower orbital arch to the cephalic margin of the tragus of the ear<sup>13</sup>

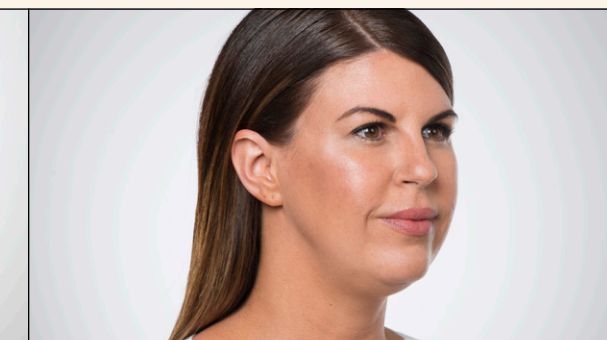
## CAPTURE PHOTOS IN THESE ANGLES BEFORE EVERY TREATMENT SESSION



FRONTAL



LATERAL  
(right and left sides)



OBLIQUE



## HELPFUL HINT

Draw the sloped chin profile line over the photo to emphasize the submental area.

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# Talk About *Treatment*

Patients look to you for information. Ensure that your appropriate candidates for KYBELLA® understand the key points about what it is, how it works, and risks with treatment.



## Common conversations to guide your discussions with patients:

“  
**Your double chin could be genetic.**  
”

Reassure patients that you don't have to be overweight to have fullness under your chin. Both men and women may be affected by submental fullness, which can be caused by weight gain, aging, and genetics. Exercise or diet may not impact submental fat.<sup>14</sup>

“  
**KYBELLA® can help improve your chin profile.<sup>1</sup>**  
”

The phrase “double chin” may be a sensitive subject for some patients. Talking to patients about the sloped chin profile line is an alternative way to bring up submental fullness and educate patients on KYBELLA®.

“  
**KYBELLA® is a series of treatments with progressive results.<sup>1</sup>**  
”

Communicate the progressive nature of the treatment with appropriate patients. Patients may not see the results they're hoping for after only 1 session. Remember, 59% of clinical trial patients received 6 KYBELLA® treatments.<sup>1</sup>

“  
**You may be an appropriate candidate.**  
”

Let patients know why they are an appropriate candidate for KYBELLA®. Make sure they understand KYBELLA® is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.<sup>1</sup>

“  
**There are safety considerations for treatment and potential side effects.**  
”

Be sure to fully assess the patient's submental area, including excessive skin laxity, prominent platysmal bands, and prior surgical or aesthetic treatment of the submental area that may impact their candidacy for treatment with KYBELLA®.<sup>1</sup> Ensure that there is no infection at the injection sites.<sup>1</sup> Educate all candidates about the potential side effects. (See more information about side effects on page 17.)

“  
**The fat cells in the treatment area are permanently destroyed with KYBELLA®.<sup>1</sup>**  
”

A reminder that KYBELLA® destroys the fat cells under the patient's chin is an excellent reinforcement of the importance of adherence to the treatment plan.

“  
**We can tailor a treatment plan to meet your aesthetic goals.<sup>1</sup>**  
”

Patients may value hearing that their anatomy is unique to them. With KYBELLA®, the number of treatments can be tailored to the patient's amount of submental fat and their particular aesthetic goals.\*

\*Multiple injections under the chin per treatment; up to 6 treatments at least 1 month apart.<sup>1</sup> In clinical trials, 59% of subjects received 6 KYBELLA® treatments.<sup>1</sup>

### INDICATION

KYBELLA® (deoxycholic acid) injection is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.

The safe and effective use of KYBELLA® for the treatment of subcutaneous fat outside the submental region has not been established and is not recommended.

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### IMPORTANT SAFETY INFORMATION

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## Set Expectations

Patient education is important. Consultation is a good time to introduce them to the treatment planning process.

## Discuss Safety

Prepare your patient for potential swelling or other adverse injection-site reactions. The most common adverse reactions were primarily associated with the treatment area.<sup>1</sup>

**“You are probably a 4+.”**

In clinical studies, most adults saw visible results after 2 to 4 treatments<sup>1,15</sup>—patients may not see the results they’re hoping for after only 1 session. In fact, in clinical trials, 59% of patients received 6 KYBELLA® treatments.<sup>1</sup>

**“You should prepare for expected swelling.”**

Manage your patients’ expectations regarding possible side effects. The most common adverse reactions seen in clinical trials were primarily associated with the treatment area<sup>1</sup> and were mild or moderate in severity. The incidence and severity of swelling decreased with subsequent treatments.<sup>16</sup>

**To help set expectations about the number of treatments needed, Kount them into 2 groups.**



2 or 3 treatments to achieve desired aesthetic goals



4, 5, or 6 treatments to achieve desired aesthetic goals

In clinical studies, results for subjects treated with KYBELLA® who had:

- A ≥ 1-grade composite physician- and subject-rated improvement were 8% (1 treatment), 28% (2 treatments), 43% (3 treatments), 55% (4 treatments), 66% (5 treatments), and 72% (6 treatments), compared with 2% (1 treatment), 7% (2 treatments), 12% (3 treatments), 14% (4 treatments), 15% (5 treatments), and 22% (6 treatments) of subjects treated with placebo<sup>15</sup>
- A ≥ 2-grade composite physician- and subject-rated improvement were 0% (1 treatment), 0% (2 treatments), 1% (3 treatments), 4% (4 treatments), 4% (5 treatments), and 15% (6 treatments), compared with 0% (1 treatment), 0% (2 treatments), 0% (3 treatments), 1% (4 treatments), 0% (5 treatments), and 2% (6 treatments) of subjects treated with placebo<sup>15</sup>

The number of treatments is tailored\* to the amount of submental fat and aesthetic goals; 59% of subjects received 6 KYBELLA® treatments in clinical trials.<sup>1</sup>

\*Multiple injections under the chin per treatment; up to 6 treatments at least 1 month apart.<sup>1</sup>

### KYBELLA® Compared With Placebo<sup>1</sup>

Adverse reactions <sup>†</sup>	KYBELLA® (N = 513)	Placebo (N = 506)
Injection-site reactions:	96%	81%
Edema/swelling	87%	43%
Hematoma/bruising	72%	70%
Pain	70%	32%
Numbness	66%	6%
Erythema	27%	18%
Induration	23%	3%

#### For KYBELLA®-treated subjects:

- 1.6% discontinued clinical studies due to adverse reactions<sup>17</sup>
- 80.9% of adverse reactions were mild, 17.5% were moderate, and 1.6% were severe<sup>16</sup>

<sup>†</sup>Injection-site reactions that occurred in ≥ 20% of subjects treated with KYBELLA® and at a greater incidence than placebo.<sup>1</sup>

Adverse reactions that occurred in < 20% of subjects treated with KYBELLA® and at a greater incidence than placebo include injection-site reactions (paresthesia, nodule, pruritus, skin tightness, site warmth, and nerve injury [marginal mandibular nerve paresis]); headache; oropharyngeal pain; hypertension; nausea; and dysphagia. Other adverse reactions associated with KYBELLA® include injection-site hemorrhage, injection-site discoloration, presyncope/syncope, lymphadenopathy, injection-site urticaria, and neck pain. Injection-site ulceration, necrosis, infection, alopecia, and scarring are adverse administration-site reactions identified during postapproval use of KYBELLA®.<sup>1</sup>

#### IMPORTANT SAFETY INFORMATION (continued)

##### WARNINGS AND PRECAUTIONS

###### Marginal Mandibular Nerve Injury

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# Key Points to Remember



A thorough consultation should focus on patient education.



Quality photos can facilitate conversations about patients' submental fullness, their aesthetic goals, and their progressive results with KYBELLA®.



Reinforce that together, you and your patient can individually tailor\* a treatment plan for KYBELLA®, based on their unique anatomy and desired aesthetic goals. Tell patients that they need to repeat sessions until they complete the recommended plan.



Balance the discussion of KYBELLA® indication and benefits with an honest conversation about potential side effects.

\*Multiple injections under the chin per treatment; up to 6 treatments at least 1 month apart. In clinical trials, 59% of subjects received 6 KYBELLA® treatments.<sup>1</sup>

## IMPORTANT SAFETY INFORMATION (continued)

### WARNINGS AND PRECAUTIONS (continued)

#### Dysphagia

Dysphagia occurred in 2% of subjects in the clinical trials in the setting of administration-site reactions, eg, pain, swelling, and induration of the submental area; all cases of dysphagia resolved spontaneously (range 1-81 days, median 3 days). Avoid use of KYBELLA® in patients with current or prior history of dysphagia as treatment may exacerbate the condition.

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# Treat

## IMPORTANT SAFETY INFORMATION (continued)

### WARNINGS AND PRECAUTIONS (continued)

#### Injection Site Hematoma/Bruising

In clinical trials, 72% of subjects treated with KYBELLA® experienced hematoma/bruising. KYBELLA® should be used with caution in patients with bleeding abnormalities or who are currently being treated with antiplatelet or anticoagulant therapy as excessive bleeding or bruising in the treatment area may occur.

Please see additional Important Safety Information throughout.

A.C.T.

- Individualized goals
- Indication and benefits
- Tailored plan
- Aftercare and maintenance

Strengthen your injection technique using this step-by-step guide.

## Kount the Treatments

The KYBELLA® Kount (2+/4+) helps you and your patient discuss the number of treatment sessions estimated for the desired reduction of their submental fullness. Tailor the number of treatments to the submental fat severity and your patient's aesthetic goals.<sup>1</sup>

**Two or more (2+)** treatment sessions may be appropriate for patients with more moderate submental fullness.



When speaking to patients about 2+, make sure they understand the **minimum number of treatment sessions is 2 and the maximum is 6.**

- In clinical trials, 59% of patients received 6 KYBELLA® treatments<sup>1</sup>

Ensure that patients know that each treatment session may be administered at intervals no less than 1 month apart.<sup>1</sup>

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### *Risk of Injecting Into or in Proximity to Vulnerable Anatomic Structures*

To avoid the potential of tissue damage, KYBELLA® should not be injected into or in close proximity (1 cm-1.5 cm) to salivary glands, lymph nodes, and muscles. Care should be taken to avoid inadvertent injection directly into an artery or a vein as it can result in vascular injury.

**Please see additional Important Safety Information throughout.**

**Four or more (4+)** treatment sessions may be appropriate for patients with moderate to severe submental fullness.



When speaking to patients about 4+, make sure they understand the **minimum number of treatment sessions is 4 and the maximum is 6.**

- In clinical trials, 59% of patients received 6 KYBELLA® treatments<sup>1</sup>

Ensure that patients know that each treatment session may be administered at intervals no less than 1 month apart.<sup>1</sup>

### IMPORTANT REMINDER

One (1) treatment session is discouraged, as clinical studies indicated that most adults saw visible results after 2 to 4 treatments.<sup>15</sup>

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### *Injection Site Alopecia*

Cases of injection site alopecia have been reported with administration of KYBELLA®. Onset and duration may vary among individuals and may persist. Consider withholding subsequent treatments until resolution.

**Please see additional Important Safety Information throughout.**

**KYBELLA®**  
(deoxycholic acid) injection 10 mg/mL

# Kount the Treatments

## 2+ TREATMENTS

## 4+ TREATMENTS

ADRA  
AGE: 35



MARINA  
AGE: 58



JASON  
AGE: 36



PONTI  
AGE: 48



**Unretouched photos of paid models. Individual results may vary.**  
Results are represented over the course of treatment; not all treatments are shown. Number of treatments is tailored\* to the amount of submental fat and aesthetic goals; 59% of subjects received 6 KYBELLA® treatments in clinical trials.<sup>1</sup>

\*Multiple injections under the chin per treatment; up to 6 treatments at least 1 month apart.<sup>1</sup>

**Unretouched photos of paid models. Individual results may vary.**  
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\*Multiple injections under the chin per treatment; up to 6 treatments at least 1 month apart.<sup>1</sup>

**IMPORTANT SAFETY INFORMATION (continued)**

**WARNINGS AND PRECAUTIONS (continued)**

*Injection Site Ulceration, Necrosis, and Infection*

Injections that are too superficial into the dermis may result in skin ulceration and necrosis. Cases of injection site ulceration, necrosis, and infection have been reported with administration of KYBELLA®. Some cases of injection site infection have included cellulitis and abscess requiring antibiotic treatment and incision and drainage. Do not administer KYBELLA® into affected area until complete resolution.

**Please see additional Important Safety Information throughout.**

**IMPORTANT SAFETY INFORMATION (continued)**

**ADVERSE REACTIONS**

The most commonly reported adverse reactions in the pivotal clinical trials were: injection site edema/swelling, hematoma/bruising, pain, numbness, erythema, and induration.

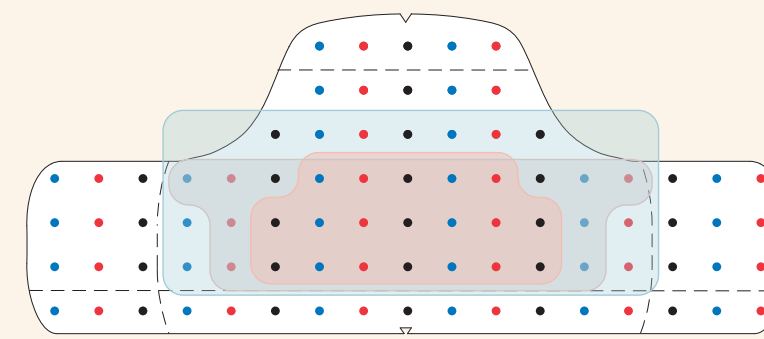
**Please see additional Important Safety Information throughout.**

**KYBELLA®**  
(deoxycholic acid) injection 10 mg/mL

# Kalculate the Vials

The number of vials that you use will depend on the patient's submental fat profile and identified Treatment Zone.<sup>1</sup> It may be useful to discuss the number of vials during a pricing conversation or for ordering purposes.

## ESTIMATE INJECTION SITES WITHIN TREATMENT AREA



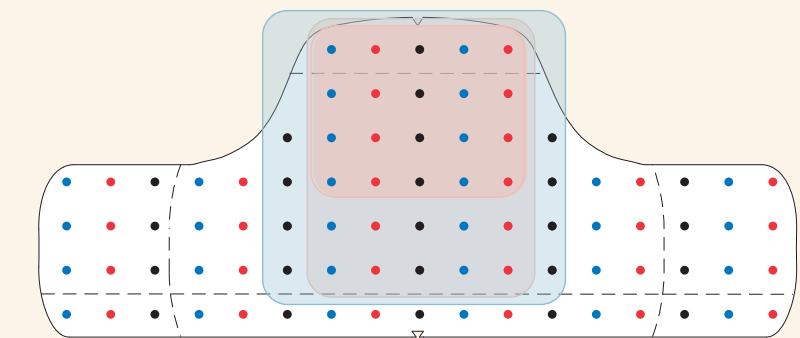
Number of dots	Number of vials <sup>1</sup>
10	1
20	2
30	3
40	4
50	5



### ESTABLISHED DOSING STANDARD<sup>1</sup>

- Dose 0.2 mL per injection site
- Space injection sites 1 cm apart
- Administer up to 50 injections per treatment session
- Do not exceed 10 mL, or 5 vials, in a single treatment session
- Results seen in the clinical trials were based on the use of the recommended dose

- Use the spacing grid (included in every package of KYBELLA<sup>®</sup>) to help plan your injections and customize treatment to the individual patient's anatomy
- Customize the size and shape of the spacing grid based on the patient's submental fat and Treatment Zone
- Count (or estimate) the number of dots

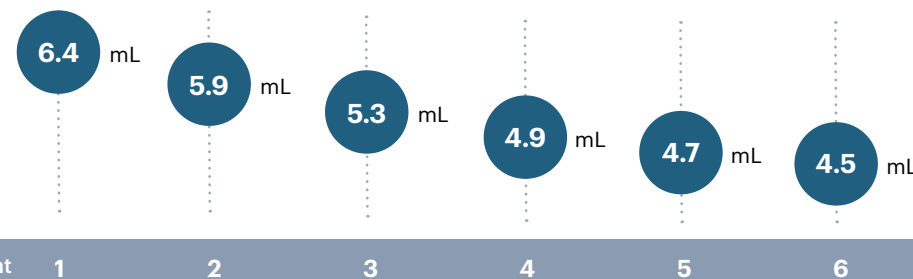


Colors of dots on image above are for visual purposes only. --- Perforations

### DID YOU KNOW?

The average total dose in clinical trials declined with each treatment.<sup>18,19</sup>

Average total dose per treatment session in clinical trials



### KALCULATE THE VIALS NEEDED PER TREATMENT SESSION<sup>1</sup>

- For every 10 dots on the spacing grid, you will need 1 vial of KYBELLA<sup>®</sup>
- Round the number up to ensure an adequate amount of KYBELLA<sup>®</sup>
- Do not exceed 5 vials (or 10 mL) in a single treatment session

### INDICATION

KYBELLA<sup>®</sup> (deoxycholic acid) injection is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.

The safe and effective use of KYBELLA<sup>®</sup> for the treatment of subcutaneous fat outside the submental region has not been established and is not recommended.

Please see additional Important Safety Information throughout.

### IMPORTANT SAFETY INFORMATION

#### CONTRAINDICATIONS

KYBELLA<sup>®</sup> is contraindicated in the presence of infection at the injection sites.

Please see additional Important Safety Information throughout.

**KYBELLA<sup>®</sup>**  
(deoxycholic acid) injection 10 mg/mL

# Prep for Injection

Prior to the treatment session, ensure that you have all the necessary supplies and that the photo session has been completed.

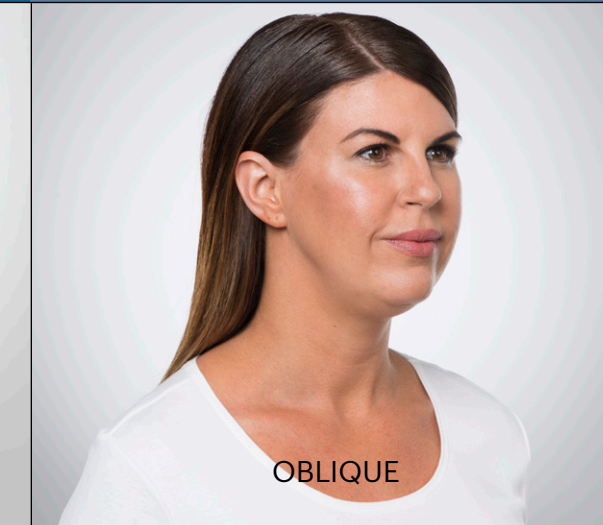
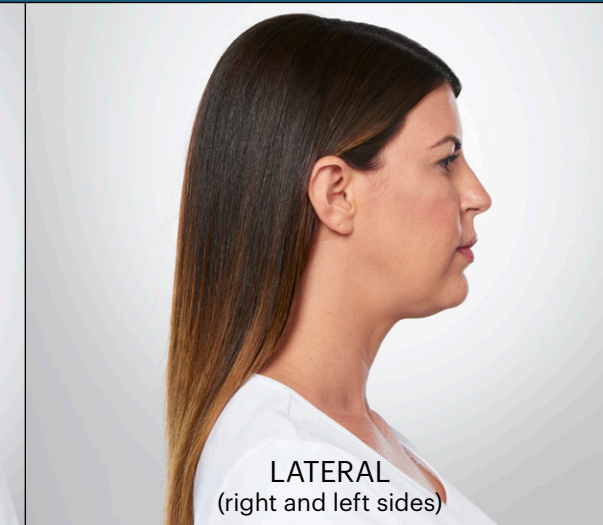
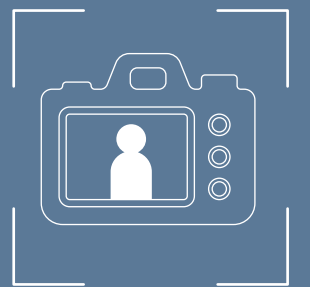
## GATHER SUPPLIES<sup>1</sup>

- Topical/injectable anesthetics
- Sterile water
- Cotton pads/balls
- Skin-marking pen/pencil
- Ruler
- Topical antiseptic
- Skin-marking, 1-cm<sup>2</sup> injection grid
- Scissors
- Cold compress or ice pack
- Isopropyl alcohol
- Gauze
- 1-mL syringes
- A large-bore needle (eg, 21 G)
- 30-G (or smaller), 0.5-inch needles
- KYBELLA<sup>®</sup> 2-mL vials



## TAKE PHOTOS

Capture photos in each view before every treatment session.



Photos are important to track treatment progress over time.

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS

##### Marginal Mandibular Nerve Injury

Cases of marginal mandibular nerve injury, manifested as an asymmetric smile or facial muscle weakness, were reported in 4% of subjects in the clinical trials; all cases resolved spontaneously (range 1-298 days, median 44 days). KYBELLA<sup>®</sup> should not be injected into or in close proximity to the marginal mandibular branch of the facial nerve.

Please see additional Important Safety Information throughout.

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### Dysphagia

Dysphagia occurred in 2% of subjects in the clinical trials in the setting of administration-site reactions, eg, pain, swelling, and induration of the submental area; all cases of dysphagia resolved spontaneously (range 1-81 days, median 3 days). Avoid use of KYBELLA<sup>®</sup> in patients with current or prior history of dysphagia as treatment may exacerbate the condition.

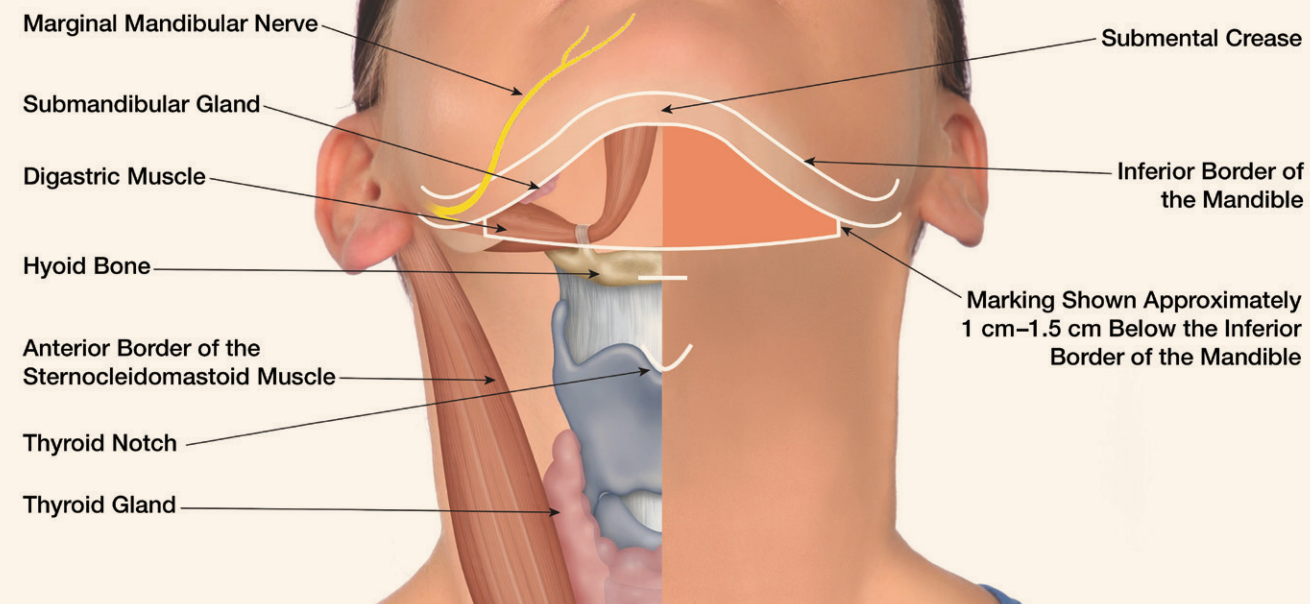
Please see additional Important Safety Information throughout.

**KYBELLA<sup>®</sup>**  
(deoxycholic acid) injection 10 mg/mL

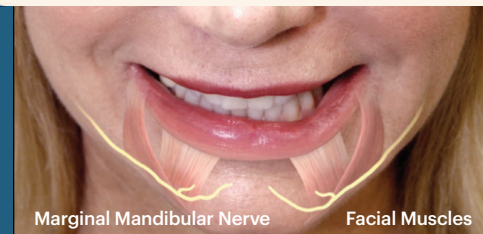
# Prep for Injection

Healthcare professionals administering KYBELLA® must understand the relevant submental anatomy and associated neuromuscular structures in the area involved or any alterations to the anatomy due to prior surgical or aesthetic procedures.

## IDENTIFY ANATOMIC LANDMARKS<sup>1,20,21</sup>



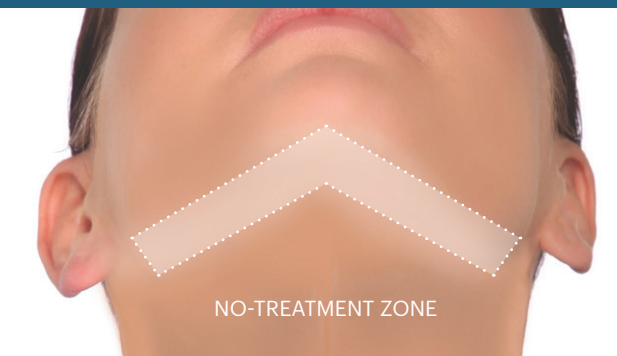
Be especially aware of the marginal mandibular nerve to reduce potential for injury.<sup>1</sup>



## MARK THE TREATMENT ZONE

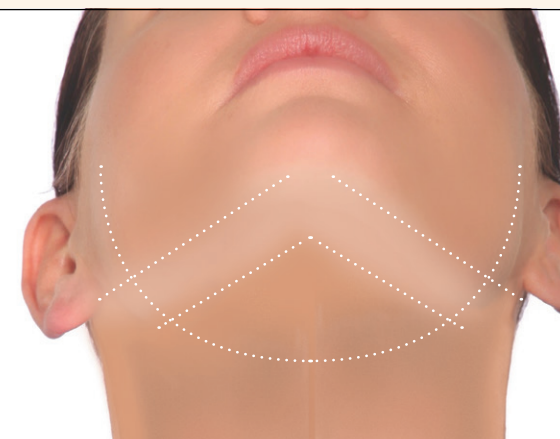
### DELINEATE THE NO-TREATMENT ZONE<sup>1</sup>

- Use a topical antiseptic to thoroughly cleanse the skin, removing all makeup before marking the Treatment Zone
- Mark the inferior border of the mandible<sup>1,20</sup>
- Mark the area 1 cm to 1.5 cm below the inferior border of the mandible<sup>1</sup>



### OUTLINE THE TREATMENT ZONE

Mark the anterior, posterior, and lateral boundaries of the submental fat compartment.<sup>1,21</sup>



### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### Injection Site Hematoma/Bruising

In clinical trials, 72% of subjects treated with KYBELLA® experienced hematoma/bruising. KYBELLA® should be used with caution in patients with bleeding abnormalities or who are currently being treated with antiplatelet or anticoagulant therapy as excessive bleeding or bruising in the treatment area may occur.

Please see additional Important Safety Information throughout.

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### Risk of Injecting Into or in Proximity to Vulnerable Anatomic Structures

To avoid the potential of tissue damage, KYBELLA® should not be injected into or in close proximity (1 cm-1.5 cm) to salivary glands, lymph nodes, and muscles. Care should be taken to avoid inadvertent injection directly into an artery or a vein as it can result in vascular injury.

Please see additional Important Safety Information throughout.

**KYBELLA®**  
(deoxycholic acid) injection 10 mg/mL

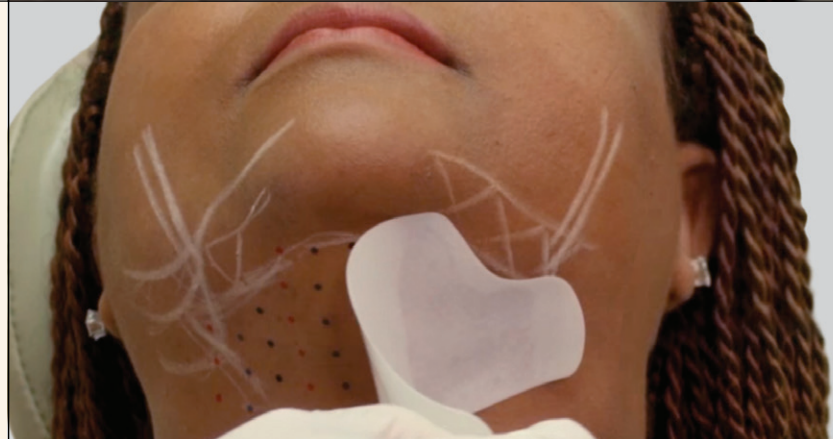
## ANESTHETIZE

Apply ice/cold packs or local anesthesia, which may enhance patient comfort.<sup>1</sup>



## APPLY GRID

- Check placement of skin-marking grid
- Remove clear protective top sheet
- Press grid onto clean, dry skin and dampen while maintaining even pressure
- Wait 15 seconds, then peel backing and assess



## CLEAN

Use a topical antiseptic to clean the treatment area gently so as not to remove markings and grid dots.



## DRAW<sup>1</sup>

Draw up all your syringes in advance using a large-bore needle.

- Draw 1 mL of KYBELLA<sup>®</sup> into a sterile 1-mL syringe
- Expel any air bubbles in the syringe barrel
- Continue until all syringes are filled
- Dilution or admixture of KYBELLA<sup>®</sup> with other compounds is not recommended

For injection, replace the large-bore needle with a 30-G (or smaller), 0.5-inch needle.

KYBELLA<sup>®</sup> is clear, colorless, and free of particulate matter. Discard vial if solution is discolored and/or contains particulate matter.<sup>1</sup>



### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### *Injection Site Alopecia*

Cases of injection site alopecia have been reported with administration of KYBELLA<sup>®</sup>. Onset and duration may vary among individuals and may persist. Consider withholding subsequent treatments until resolution.

**Please see additional Important Safety Information throughout.**

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### *Injection Site Ulceration, Necrosis, and Infection*

Injections that are too superficial into the dermis may result in skin ulceration and necrosis. Cases of injection site ulceration, necrosis, and infection have been reported with administration of KYBELLA<sup>®</sup>. Some cases of injection site infection have included cellulitis and abscess requiring antibiotic treatment and incision and drainage. Do not administer KYBELLA<sup>®</sup> into affected area until complete resolution.

#### ADVERSE REACTIONS

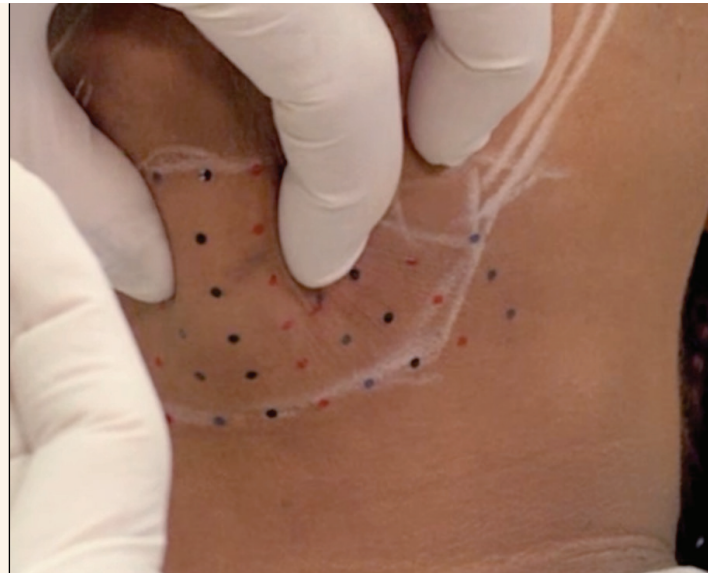
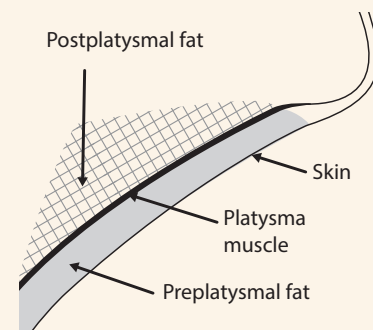
The most commonly reported adverse reactions in the pivotal clinical trials were: injection site edema/swelling, hematoma/bruising, pain, numbness, erythema, and induration.

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## PINCH<sup>1</sup>

- Start by having the patient tense the platysma muscle, then pinch the preplatysmal fat between 2 fingers



## INJECT<sup>1</sup>

- Injecting perpendicular to the skin, place 0.2 mL of KYBELLA<sup>®</sup> adjacent to each grid dot within the Treatment Zone
- Inject approximately midway into the preplatysmal fat layer



## INJECTION TECHNIQUE CONSIDERATIONS<sup>1</sup>

- Injections that are too superficial (into the dermis) may result in skin ulceration and necrosis
- If resistance is met, withdraw the needle to an appropriate depth before injecting
- Avoid injection into other tissues, such as the muscle, salivary glands, and lymph nodes
- Avoid inadvertent injection directly into an artery or vein, as this can result in vascular damage

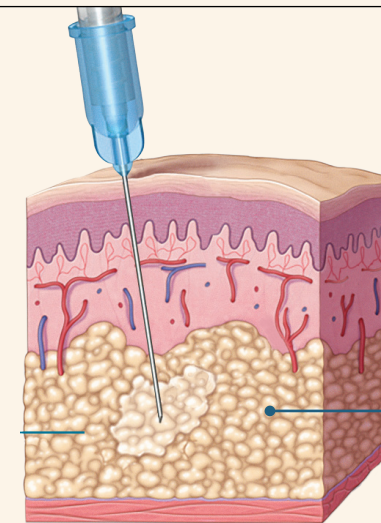


Platysma muscle

Preplatysmal fat

## WITHDRAW THE NEEDLE<sup>1</sup>

- Take your finger off the plunger as you withdraw the needle to avoid inadvertent administration in structures outside the submental fat compartment
- Apply pressure to each injection site as necessary to minimize bleeding
- Apply an adhesive dressing, if needed, for bleeding



## SUBMENTAL FAT

Do not withdraw the needle from subcutaneous fat during injection. This could increase the risk of intradermal exposure and potential skin ulceration and necrosis.<sup>1</sup>

## INDICATION

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## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

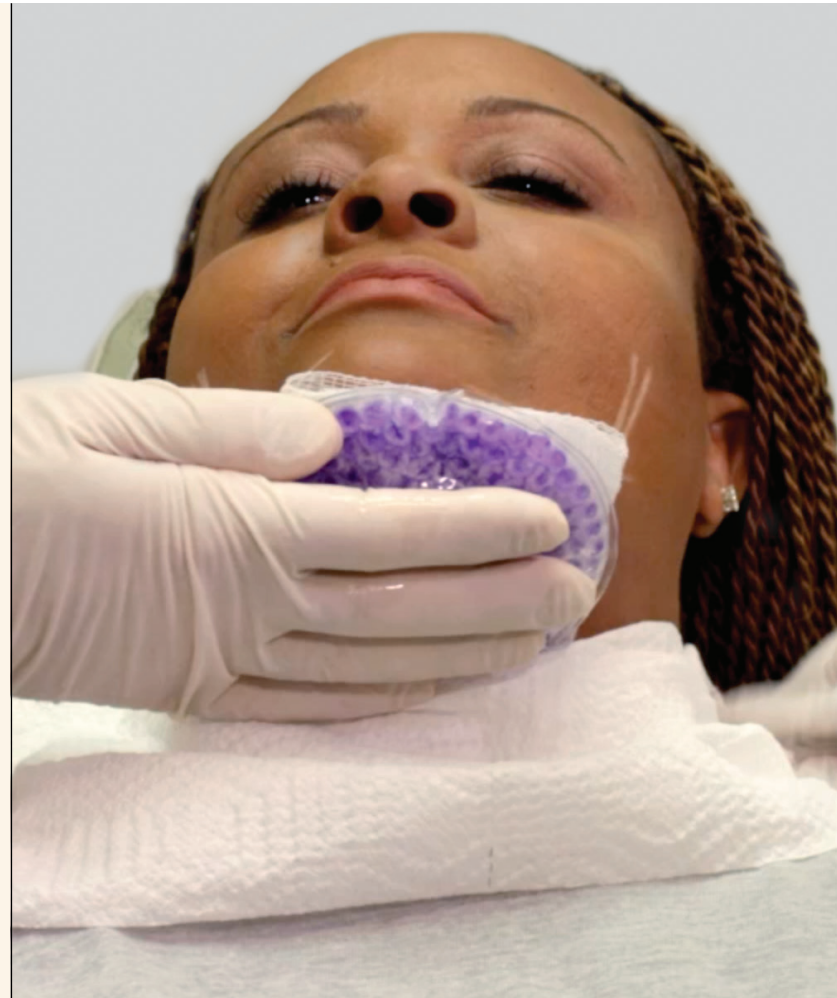
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## CONCLUDE THE TREATMENT

- Consider applying ice or a cold pack to the treatment area for 5 to 15 minutes
- Remove the grid and markings using cotton dampened with isopropyl alcohol
- Assess smiling and swallowing to screen for dysphagia or any injury to the marginal mandibular nerve



## MAKE SURE PATIENTS KNOW

- ✓ **Swelling is an expected reaction** to treatment<sup>1</sup>—it generally became less severe and happened less often with subsequent treatment sessions in clinical studies.<sup>16</sup>

**TIP:** Show patients a 1-day-posttreatment photo so they can see how swelling may look.

- ✓ **Results are progressive**—KYBELLA<sup>®</sup> permanently destroys fat cells in the submental treatment area.<sup>1</sup>
- ✓ The **recommended number of sessions** in their treatment series should achieve their aesthetic goals.<sup>1</sup>
- ✓ Each treatment is **at least 1 month apart**.<sup>1</sup>
- ✓ **Show before-and-after photos at every visit.**

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS

##### *Marginal Mandibular Nerve Injury*

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## Key Points to Remember

- ✓ Count the number of treatment sessions and calculate the number of vials per session in an effort to customize the patient's treatment series. Use this information during conversations about what to expect from treatment.
- ✓ Use established dosing standards to ensure optimal outcomes.
- ✓ Ensure that you identify and mark the patient's Treatment Zone prior to injection. The safe and effective use of KYBELLA® depends on the use of the correct number of and locations for injections, proper needle placement, and administration techniques.<sup>1</sup>
- ✓ To avoid potential tissue damage, KYBELLA® should not be injected into or in close proximity (1 cm to 1.5 cm) to salivary glands, lymph nodes, muscles, arteries, or the marginal mandibular branch of the facial nerve.<sup>1</sup>
- ✓ Encourage patients to adhere to their treatment plan in an effort to achieve their desired aesthetic goals.

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### Dysphagia

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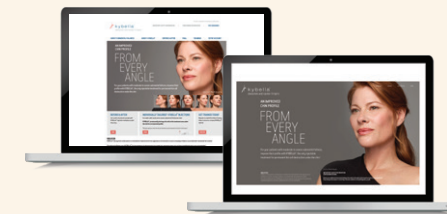
## Resources

This guide is one of many valuable resources about KYBELLA®. Review our most popular resources below and where you can find them.

BrandBox | Allergan Aesthetics

### ALLERGAN BRANDBOX

BrandBox holds many valuable resources that bring many of the topics covered in this guide to life.



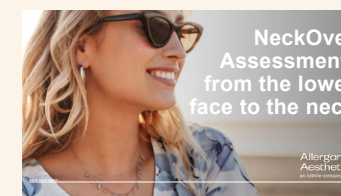
### HEALTHCARE PROVIDER WEBSITE

The provider website at [hcp.kybella.com](http://hcp.kybella.com) holds great information and additional learning opportunities about KYBELLA®.

Allē

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### NECKOVER ASSESSMENT

Provides a step-by-step protocol to assess patient concerns about the lower face, submental area, and neck.



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**KYBELLA®**  
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ASSESS.  
CONSULT.  
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Real patient.  
Results may vary.

A.C.T. on your  
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(1-844-639-2246)**

**IMPORTANT SAFETY INFORMATION (continued)**

**WARNINGS AND PRECAUTIONS (continued)**

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**IMPORTANT SAFETY INFORMATION (continued)****WARNINGS AND PRECAUTIONS (continued)***Risk of Injecting Into or in Proximity to Vulnerable Anatomic Structures*

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Please see accompanying full Prescribing Information or visit [https://www.rxabbvie.com/pdf/kybella\\_pi.pdf](https://www.rxabbvie.com/pdf/kybella_pi.pdf)

References: 1. KYBELLA® Prescribing Information, October 2024. 2. Mejia JD, Nahai FR, Nahai F, Momoh AO. Isolated management of the aging neck. *Semin Plast Surg.* 2009;23(4):264-273. 3. Ramirez OM. Advanced considerations determining procedure selection in cervicoplasty. Part one: anatomy and aesthetics. *Clin Plast Surg.* 2008;35(4):679-690. 4. Gyskiewicz JM. Submental suction-assisted lipectomy without platysmaplasty: pushing the (skin) envelope to avoid a face lift for unsuitable candidates. *Plast Reconstr Surg.* 2003;112(5):1393-1405. 5. Dayan SH, Bassichis B, Greene RM, Patel AB. Neck rejuvenation. In: Hirsch R, Sadick N, Cohen JL, eds. *Aesthetic Rejuvenation: A Regional Approach.* McGraw-Hill Professional; 2008:123-148. 6. Connell BF, Hosn W. Importance of the digastric muscle in cervical contouring: an update. University of California, Irvine: American Society for Aesthetic Plastic Surgery; 2000. 7. Fattahi T. Submental liposuction versus formal cervicoplasty: which one to choose? *J Oral Maxillofac Surg.* 2012;70(12):2854-2858. 8. Caplin DA, Perlyn CA. Rejuvenation of the aging neck: current principles, techniques, and newer modifications. *Facial Plast Surg Clin North Am.* 2009;17(4):589-601. 9. Smith RM, Papel ID. Difficult necks and unresolved problems in neck rejuvenation. *Clin Plastic Surg.* 2018;45(4):611-622. 10. Fedok FG, Chaikhoutdinov I, Garritano F. The difficult neck in facelifting. *Facial Plast Surg.* 2014;30(4):438-450. 11. DeFatta R, Ducic Y. Liposuction of the face and neck. *Oper Tech Otolaryngol.* 2007;18(3):261-266. 12. De Castro CC. Anatomy of the neck and procedure selection. *Clin Plast Surg.* 2008;35(4):625-642. 13. Data on file, Allergan; Integrated Summary of Efficacy: ATX-101. 14. Schlessinger J, Weiss SR, Jewell M, et al. Perceptions and practices in submental fat treatment: a survey of physicians and patients. *Skinmed.* 2013;11(1):27-31. 15. Data on file, Allergan, September 29, 2015; Composite 1- and 2-grade responders. 16. Data on file, Allergan; Integrated Summary of Safety: ATX-101. 17. Data on file, Allergan, February 20, 2015; Study discontinuation rate (ATX-101-11-22 and ATX-101-11-23) [Memo to file]. 18. Data on file. Allergan Aesthetics, an AbbVie company. ABVRR181149. 19. Data on file. Allergan Aesthetics, an AbbVie company. ABVRR181122. 20. Drake RL, Vogl AW, Mitchell AWM, Tibbitts RM, Richardson PE, eds. *Gray's Atlas of Anatomy.* 2nd ed. Churchill Livingstone; 2015. 21. Hatfeg DA, Koshiy JC, Sandoval SE, Echo AP, Izaddoost SA, Hollier LH. The submental fat compartment of the neck. *Semin Plast Surg.* 2009;23(4):288-291.