Understanding Pseudobulbar Affect (PBA)

A Guidebook for Taking Action

Do you ever laugh or cry without feeling happy or sad?

PBA is more common than you might think. It affects an estimated 1.8 million people in the United States—and it's commonly undiagnosed or misdiagnosed.

Mary-Beth is a real patient living with PBA.

Image reflects patient's health status at the time the image was captured.

"I felt like a puppet and someone else was pulling the strings."

- Mary-Beth, living with PBA

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"[The crying] came out of nowhere. I had no idea what was going on. I didn't feel sad or depressed.

After receiving my PBA diagnosis, it was such a relief. I knew what I had. I knew that it had a specific name and there was a specific treatment for it."

- Carol, living with PBA

About



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About PBA

Pseudobulbar affect (PBA) is a neurological condition that causes involuntary, sudden, and frequent episodes of crying and/or laughing. PBA episodes are typically exaggerated or don't match how a person feels.

Signs and Symptoms of PBA

PBA can be characterized by episodes of laughing or crying that are:



Involuntary

"It happens in public. I can't control it."



Sudden

"I cry for no reason. It comes out of the blue."



Frequent

"I cry more than I used to. The littlest thing sets me off."



Exaggerated

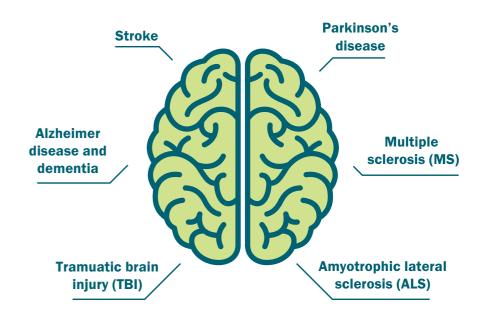
"I overreact to things now. My response is excessive."



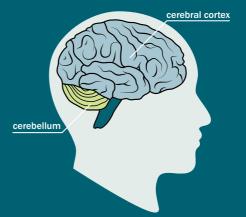
Incongruent

"I don't know why I am laughing. It's not funny."

Common Neurological Conditions or Brain Injuries that Can Lead to PBA:



What Causes PBA



Damage to the cerebral cortex or cerebellum due to a neurologic condition or brain injury may lead to miscommunication with the cerebral cortex. Since this is the part of the brain that controls emotional responses, the resulting miscommunication is thought to be the cause of PBA episodes.

Life with PBA

PBA is not a "one-size-fits-all" experience. It can occur after a trauma to the brain or secondary to another neurologic condition. Some people experience uncontrollable laughing episodes. Some people experience uncontrollable crying episodes. In some individuals—both can be present. Each person's experience with PBA is as unique as the individuals themselves.

"It was humiliating. I didn't understand what was happening at all. When you laugh at a painful time, people think you aren't empathetic. Or maybe they think you are cruel or evil. It's not like I had a hiccup or sneeze. I can't say excuse me. I can't defend myself."

- Jill, living with PBA



"During an episode, the uncontrollable crying I experience is so severe, that if one occurs while my husband and I are together at a restaurant or store, people stop and stare. It's embarrassing."

- Carol, living with PBA

Finding

Answers

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Finding Answers

PBA Is Not Depression

PBA is considered to be under-recognized, under-diagnosed, and often misdiagnosed. It is estimated, 1.8 million people in the US are living with PBA.

Although PBA can be misdiagnosed as depression, they are separate and treatable conditions. However, some people may experience both PBA and depression.

57.5%

of patients who were diagosed with PBA had comorbid depression*

In a 90-day, open-label, single-arm study, more than half of patients who were diagnosed with PBA had comorbid depression (N=367). 70.8% of patients in the study were taking psychopharmacologic medications.

*PRISM II was a 90-day, open-label, single-arm, 74-site US trial in adult patients with dementia, stroke, or traumatic brain injury. All patients received a clinical diagnosis of PBA by their healthcare provider and had a Center for Neurologic Study-Lability Scale (CNS-LS) score of ≥13 at baseline. CNS-LS is a self-administered questionnaire, designed to be completed by the patient with a 7-item rating scale that measures perceived frequency and severity of PBA episodes. It was validated as a screening tool in amyotrophic lateral sclerosis and multiple sclerosis populations. A CNS-LS score of ≥13 may suggest but does not confer a PBA diagnosis.

How Crying in PBA and Depression are Different

	Crying in PBA	Crying in Depression
How long and how often?	PBA episodes are brief	Depression symptoms can last weeks to months
Can you control it?	PBA episodes are often explosive and unpredictable	Depression is consistent crying with a persistent feeling of sadness
Does it match your mood?	Emotional response is considered inappropriate to a situation, exaggerated, and involuntary	Other symptoms can include fatigue, insomnia, and feelings of hopelessness

Impact of PBA

Pseudobulbar affect (PBA) may present a considerable burden in addition to the difficulties of living with a neurologic condition or brain injury. PBA episodes can be very frustrating for individuals experiencing them, as well as for those around them, because the episodes can be misunderstood and easily lead to confusion and embarrassment.

It's important to know that you are not alone. Many patients living with PBA have had similar experiences. It's important to assess the impact individually and take action by advocating for yourself with your healthcare providers.

"[The crying] came out of nowhere. I had no idea what was going on. I didn't feel sad or depressed. After receiving my PBA diagnosis, it was such a relief. I knew what I had. I knew that it had a specific name and there was a specific treatment for it."

Carol, living with PBA

How PBA Is Diagnosed

PBA is typically diagnosed during a neurological exam by a specialist who is experienced in treating brain injuries or neurological conditions. Not all doctors may be familiar with the condition. It is important to find a provider who can diagnose and treat PBA.

Neurologist Psychiatrist Neuropsychiatrist

Internist Physiatrist Brain Injury Specialist

While there is no definitive test to diagnose PBA, doctors may use a screening tool like the Center for Neurologic Study-Lability Scale (CNS-LS) as a part of their evaluation. They will assess the patient and provide a diagnosis based on a thorough understanding of:

- Symptoms
- Medical history, especially the existence of a primary neurologic condition or brain injury
- Mental health history
- Findings from a physical exam

PBA May Be Difficult to Diagnose

Patients living with a neurologic condition or brain injury may find that the process of getting an accurate diagnosis for a secondary condition like PBA is not always straightforward. It's not uncommon to feel emotional, tearful, stressed, or confused at times when dealing with the challenges of living with a neurologic condition or brain injury. Doctors may attribute the uncontrollable crying and/or laughing to mood changes or symptoms associated with their primary condition.

Not only do different patients experience PBA symptoms in different ways, but the episodes can also be difficult to understand and challenging to describe to a doctor. PBA is frequently mistaken for depression because of the overlap with symptoms of mood disorders and other conditions. All of these factors may complicate the diagnosis process.

The important thing to remember is that PBA is a separate neurologic condition of emotional expression that is caused by damage to the brain and that it can be treated.



Talking to Your Doctor

Once you find a healthcare provider who can diagnose and treat PBA, consider what you need to have a successful conversation about your concerns. Advocating for yourself and coming to appointments prepared with information can help your doctor understand your unique situation.

Your provider may ask you the following questions during your appointment:

Have you been diagnosed with any underlying conditions?

Do you experience uncontrollable outbursts of laughing, crying, or both?

When did you first start experiencing episodes? How often and for how long do they last?

What is your current method of managing episodes?

How are episodes impacting you? Do you find episodes to be disruptive to your life?

How frequent are your episodes and what is the duration/disruption?

"I would suggest bringing specific incidences [to] give the doctor what they need to [make an accurate diagnosis]."

- Mary-Beth, living with PBA

One Person's Journey:

Mary-Beth's journey to diagnosis lasted 11 years and included being misdiagnosed, despite visits to many different doctors. She describes her emotional journey with feelings of self-consciousness and embarrassment. Mary-Beth says she felt dismissed, uncomfortable, and judged. In her own words, she shares her experience of being diagnosed:



"My neuropsychiatrist was incredible and very supportive through my diagnosis—before, during, and after, as well as in starting treatment. She never gave up on solving this with me. She explained how this is a neurological condition—not a mental health one."

- Mary-Beth, living with PBA

What's

Next?

Built into this workbook are resources to help prepare you for meeting with a doctor, including a PBA symptom tracker and a doctor discussion guide.

- The doctor discussion guide is intended to help you have an empowered discussion with your doctor about symptoms, the impact, your goals, and the available treatment options that may be right for you.
- The Symptom Journal is designed to capture and log trends for a three-week period. It can help you identify some of the important details about your episodes and help you answer questions your doctor may ask when evaluating you for PBA.

What's Next?

If you think you may have PBA, getting a diagnosis from a healthcare provider who can diagnose and treat PBA is the first step. From there, you can choose the right support, management, and treatment options for you.

Need help finding a specialist? Click below.

Find a Specialist



"If I had to sum up what my brain injury and PBA journey have taught me, I'd say I learned how important it is to advocate for yourself, be persistent, and not lose hope. Today, I'm hopeful about a life with fewer PBA episodes."

- Carol, living with PBA

Managing and Treating PBA

Once you are diagnosed with PBA:

Talk with other people who have PBA. They understand what it's like and might have other tips that could help you.

Find some ways to help yourself cope during episodes. This could include distracting yourself; taking slow, deep breaths; relaxing your body; changing your position; holding a loved one's hand; or changing the scenery.

Do not stop a treatment or management plan without first consulting your care provider.

Follow up on all medical appointments, and communicate openly about your experience.

Consider sharing your diagnosis with friends and family. It might help to explain to family, friends, and coworkers how the condition affects you so they aren't surprised or confused by your behavior.

Ask your doctor about treatment options that may be right for you.

Continue to track the frequency and duration of episodes for further discussion with your doctor.

Myths vs Facts about PBA

Pseudobulbar affect (PBA) episodes can be disruptive, confusing, and upsetting. Because PBA symptoms can look a lot like depression or other common mood disorders, it can be hard to understand and recognize as a separate and treatable condition before a formal diagnosis.

Myth

PBA is a psychiatric condition.

FACT

PBA is a **neurologic condition**, not a psychiatric one.

Myth

You can "control" laughing and/or crying episodes.

FACT

PBA is **uncontrollable** exaggerated laughing or crying isn't your fault.

Advocate for Yourself

Not all doctors may consider PBA right away. Some may consider your symptoms to be related to your primary or underlying neurologic condition or brain injury. Others may consider depression before exploring PBA, especially if they aren't familiar with it. That's why what you share with them is so important.

No one knows you better than yourself. It's OK to let your doctor know if something doesn't seem right to you. If you receive a treatment for your uncontrollable crying and/or laughing and you don't notice an improvement, make sure you let your doctor know.

"I know this can be a hard path to walk, but I encourage you to keep looking for the answers. Advocate for yourself. It can be hard, but no one is going to be better at advocating for you than you."

- Karen, living with PBA

Doctor Discussion

Guide

SYMPTOM JOURNAL

Doctor Discussion Guide

Preparing to Meet with the Doctor

To make the most out of your doctor visit, it's important to prepare ahead. Sometimes it's hard to remember everything you'd like to discuss with your doctor and difficult to answer all their questions in the moment. This section can help you organize your thoughts in advance based on the typical questions healthcare providers commonly ask when evaluating patients for PBA.

This includes:

- Questions you may be asked about your symptoms
- The impact of your symptoms and how they affect your day-to-day
- Things you want to ask the doctor

Information to Share with Your Doctor

I experience uncontrollable outbursts of emotions that display as: Laughing Crying Describe additional details about your symptoms: **Questions Your Doctor May Ask You** Have you been diagnosed with a neurological condition or brain injury such as: Stroke Alzheimer's disease or dementia Traumatic brain injury (TBI) Parkinson's disease ALS (amyotrophic lateral sclerosis) MS (multiple sclerosis) Other: _____ Would you describe your episodes or symptoms as any of the following? Uncontrollable Frequent Sudden Exaggerated (longer or more intense than expected) Incongruent with mood (not matching how you feel) Disruptive **Embarrassing** Uncomfortable Describe any additional details about your symptoms:

When were your episodes or symptoms first experienced?	What additional o	concerns or considerations are important to share?
Average number of episodes you experience per day or per week:	If I have PBA, wha	at treatment options are available?
Most recent number of episodes you've experienced in one week:	Would I be a good	d candidate for NUEDEXTA® (dextromethorphan HBr and quinidine sulfate)
Average duration of episodes:	Can you please to effects?	ell me how NUEDEXTA is thought to work and about potential side
Are your episodes increasing in frequency or severity?	Is NUEDEXTA cov	vered by my insurance?
What triggers your episodes?		
What diggers your opisodes:	What is the dosin medication?	ng for NUEDEXTA, and what should I expect when starting the
Current or previous method of managing episodes:		
	What additional o	concerns or considerations are important to share?
How are episodes impacting you?		

IMPORTANT SAFETY INFORMATION:

INDICATION:

NUEDEXTA is approved for the treatment of Pseudobulbar Affect (PBA).

PBA is a medical condition that causes involuntary, sudden, and frequent episodes of crying and/or laughing in people living with certain neurologic conditions or

brain injury. PBA episodes are typically exaggerated or don't match how the person feels. PBA is distinct and different from other types of emotional changes caused by neurologic disease or injury.

NUEDEXTA is only available by prescription.

Please see additional Important Safety Information on the following pages.

"I burst into a fit of laughter at nothing at all. I felt like a bobble doll, as if my head were suspended in the air, except for the rhythmic shaking from unstoppable laughter. The class fell silent. The only thing I could feel was my self-consciousness."

- Mary-Beth, living with PBA

Symptom

Journal

Symptom Journal

episodes throughout the day. It's also a great tool to share with your doctor.

DAY:	DATE:	TIME:
Symptoms Exp Laughing		Length of episode(s):
	number of episode(s) cons n comparison to the situati	sistent with your mood at the time? Were they on?
	doing at the time of the as there a trigger?	How did you feel about the episode(s)?
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"I never want a woman to be told, 'You're just emotional' or 'It must be your hormones.' I don't want anyone to feel like what is happening to them is all in their head, because that's what I thought when it started for me."

- Karen, living with PBA

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"I would encourage others with PBA—especially the skeptical ones like me—to not give up the hope that they'll find something that can help them with managing their disease."

– Jill, living with PBA

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Symptoms Expe		Length of episode(s):
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•	doing at the time of the as there a trigger?	How did you feel about the episode(s)?			



IMPORTANT SAFETY INFORMATION (continued):

Before you take NUEDEXTA, tell your doctor:

- If you are taking monoamine oxidase inhibitors (MAOIs), quinidine, or quinidine-related drugs. These can interact with NUEDEXTA causing serious side effects. MAOIs cannot be taken within 14 days before or after taking NUEDEXTA.
- If you have previously had an allergic reaction to dextromethorphan, quinidine or quinidine-like drugs
- About all medicines, herbal supplements, and vitamins you take as NUEDEXTA and certain other medicines can interact causing side effects.
- If you have had heart disease or have a family history of heart rhythm
 problems. NUEDEXTA may cause serious side effects, including changes in
 heart rhythm. If you have certain heart problems, NUEDEXTA may not be right
 for you. Your doctor may test your heart rhythm (heartbeats) before you start
 NUEDEXTA.
- If you have myasthenia gravis.

While taking NUEDEXTA, call your doctor right away:

- If you feel faint or lose consciousness.
- If you experience lightheadedness, chills, fever, nausea, or vomiting as these may be signs of an allergic reaction to NUEDEXTA. Hepatitis has been seen in patients taking quinidine, an ingredient in NUEDEXTA.
- If you have unexplained bleeding or bruising. Quinidine, an ingredient in NUEDEXTA, can cause a reduction in the number of platelets in your blood which can be severe and, if left untreated, can be fatal.
- If you feel dizzy, since it may increase your risk of falling.
- If you have muscle twitching, confusion, high blood pressure, fever, restlessness, sweating, or shivering, as these may be signs of a potential drug interaction called serotonin syndrome.

The most common side effects of NUEDEXTA include: diarrhea, dizziness, cough, vomiting, weakness, and swelling of feet and ankles. This is not a complete list of side effects. Tell your doctor about any side effect that bothers you or does not go away.

You are encouraged to report side effects of NUEDEXTA® (dextromethorphan HBr and quinidine sulfate). Please contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

Please see FULL PRESCRIBING INFORMATION.

Please see the Brief Summary of Important Facts at the end of this booklet.





IMPORTANT FACTS

NUEDEXTA

(dextromethorphan HBr and quinidine sulfate) capsules $\frac{20 \text{ mg}}{10 \text{ mg}}$

(Pronounced: new-DEX-tuh)

ABOUT NUEDEXTA

- NUEDEXTA® is approved for the treatment of Pseudobulbar Affect (PBA). PBA is a medical condition that causes involuntary, sudden, and frequent episodes of crying and/or laughing in people living with certain neurologic conditions or brain injury. PBA episodes are typically exaggerated or don't match how the person feels. PBA is distinct and different from other types of emotional changes caused by neurologic disease or injury.
- NUEDEXTA is only available by prescription.

DO NOT TAKE NUEDEXTA IF YOU

- Are taking other drugs that contain quinidine, quinine, or mefloquine.
- Have a history of allergic reactions or intolerance (including hepatitis, low blood cell count, or lupus-like syndrome) to quinidine, quinine, or mefloquine.
- Have ever been allergic to dextromethorphan (commonly found in some cough medicines).
- Are taking, or have taken, drugs called monoamine oxidase inhibitors (MAOIs). MAOIs cannot be taken within 14 days before or after taking NUEDEXTA.
- Have had heart disease or have a family history of heart rhythm problems.
- Are taking drugs such as thioridazine and pimozide that interact with NUEDEXTA and cause changes in heart rhythm.
- If you have certain heart conditions or are taking certain medicines, your doctor may test your heart rhythm (heartbeats) before you start NUEDEXTA.

NUEDEXTA MAY CAUSE SERIOUS SIDE EFFECTS

- Stop NUEDEXTA if these side effects occur:
 - Symptoms including lightheadedness, chills, fever, nausea, or vomiting may be a sign of an allergic reaction, or thrombocytopenia which if left untreated can be fatal.
 - Hepatitis has been seen in patients taking quinidine, an ingredient in NUEDEXTA.
 - Abnormal heart rhythm. Stop NUEDEXTA and tell your doctor immediately as it may be a sign of Torsades de Pointes.
- In some cases NUEDEXTA can interact with antidepressants causing confusion, high blood pressure, fever, restlessness, sweating, and shivering. Tell your doctor if you experience any of these side effects.
- Tell your doctor if you've ever been diagnosed with myasthenia gravis.
 If so, NUEDEXTA may not be right for you.

POSSIBLE COMMON SIDE EFFECTS OF NUEDEXTA

The most common side effects in patients taking NUEDEXTA were diarrhea, dizziness, cough, vomiting, weakness and swelling of feet and ankles.

- If you are unsteady on your feet or if you have fallen before, be careful while taking NUEDEXTA to avoid falling.
- · This is not a complete list of side effects.
- Tell your doctor if you have any side effect that bothers you or does not go away.

TAKING NUEDEXTA ALONG WITH OTHER MEDICATIONS

- Tell your doctor about all medicines, supplements, and vitamins you take before starting NUEDEXTA.
- NUEDEXTA may interact with other medications causing potentially serious side-effects, and may affect the way NUEDEXTA or these other medicines work. Your doctor may adjust the dose of these medicines if used together with NUEDEXTA:
 - Antidepressants.
 - Certain heart or blood pressure medications. Your doctor may test your heart rhythm before you start NUEDEXTA.
 - o Digoxin.
 - Alcohol. Limit alcohol intake while taking NUEDEXTA.
 - These are not the only medicines that may cause problems when you take NUEDEXTA.
- Before starting a new medicine, remind your doctor if you are taking NUEDEXTA.

ADDITIONAL IMPORTANT INFORMATION

- If your PBA symptoms do not improve or if they get worse, contact your healthcare provider.
- NUEDEXTA has not been studied in patients less than age 18 or in pregnant women. Tell your doctor if you may be pregnant.
- Nursing mothers: Because many drugs are excreted in human milk, discuss with your healthcare provider if you are nursing.
- Take NUEDEXTA exactly as your doctor prescribes it.
- You and your healthcare provider should talk regularly about whether you still need treatment with NUEDEXTA.
- NUEDEXTA may be taken with or without food.
- Keep NUEDEXTA and all medicines out of reach of children.
- The need for continued treatment should be reassessed periodically, as spontaneous improvement of PBA occurs in some patients.

NEED MORE INFORMATION?

This information about NUEDEXTA is important but is not complete. To learn more:

- · Talk to your healthcare provider or pharmacist
- Visit www.Nuedexta.com for FDA-approved Prescribing Information or call 1-855-4NUEDEX (1-855-468-3339).

NEED PRESCRIPTION ASSISTANCE?

 Call 1-855-4NUEDEX (1-855-468-3339) to speak with a member of our support team for tips, tools and co-pay information.

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