

For children 1 year of age and older with **SHORT BOWEL SYNDROME (SBS)** who are dependent on parenteral support (PS)

LESS PARENTERAL SUPPORT. MORE TIME DOING WHAT THEY LOVE.

GATTEX® (teduglutide) is a prescription treatment that may help reduce your child's need for parenteral support (PS), which ranges from IV hydration to total parenteral nutrition (TPN).*



ACTORS
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*In a 6-month study of 59 children, 69% (18/26) of children treated with GATTEX reduced their weekly volume of PS by 20% or more. 38% (10/26) of children treated with GATTEX achieved at least 1 day off of PS per week.

What is GATTEX?

GATTEX® (teduglutide) for subcutaneous injection is a prescription medicine used in adults and children 1 year of age and older with Short Bowel Syndrome (SBS) who need additional nutrition or fluids from intravenous (IV) feeding (parenteral support). It is not known if GATTEX is safe and effective in children under 1 year of age.

What is the most important information I should know about GATTEX?

GATTEX may cause serious side effects including making abnormal cells grow faster, polyps in the colon (large intestine), blockage of the bowel (intestines), swelling (inflammation) or blockage of the gallbladder or pancreas, and fluid overload.

Please see additional Important Safety Information throughout, click for full [Prescribing Information and Medication Guide](#), and discuss any questions with your child's doctor.

**Gattex**[®]
(teduglutide) for injection

SBS is a serious and chronic malabsorption disorder

Short bowel syndrome (SBS) occurs when parts of the intestine are removed surgically and the remaining intestine may not be able to absorb enough nutrients from food and drink

In children, this kind of surgery typically happens because of a condition at birth, including, but not limited to:

- Death of intestinal cells (necrotizing enterocolitis)
- Stomach wall defects (gastroschisis)
- Twisting of the intestine (volvulus)
- Blockage in the intestine (intestinal atresia)
- Missing nerve cells in the intestine (Hirschsprung's disease)
- Other congenital (birth) defects

SBS results in malabsorption. It puts people at risk for:



Malnutrition



Dehydration



Electrolyte disturbances



Diarrhea/increased outputs

There are multiple factors a doctor may use to determine an SBS diagnosis, not just the length of remaining bowel

SBS management

Important treatment goals for children with SBS include:

- Maintaining essential nutrition and hydration
- Helping the intestine adapt so it can properly digest nutrients and fluids
- Improving daily life by supporting healthy sleep and social habits
- Reducing or eliminating the need for long-term parenteral support

Many children with SBS require parenteral support (PS)

PS is any kind of nutrition and/or fluids that are given through a vein (intravenously). Based on your child's needs, PS can include a mix of ingredients, such as proteins, carbohydrates, fats, vitamins, and minerals.

PS requirements can vary based on your child's nutritional needs:



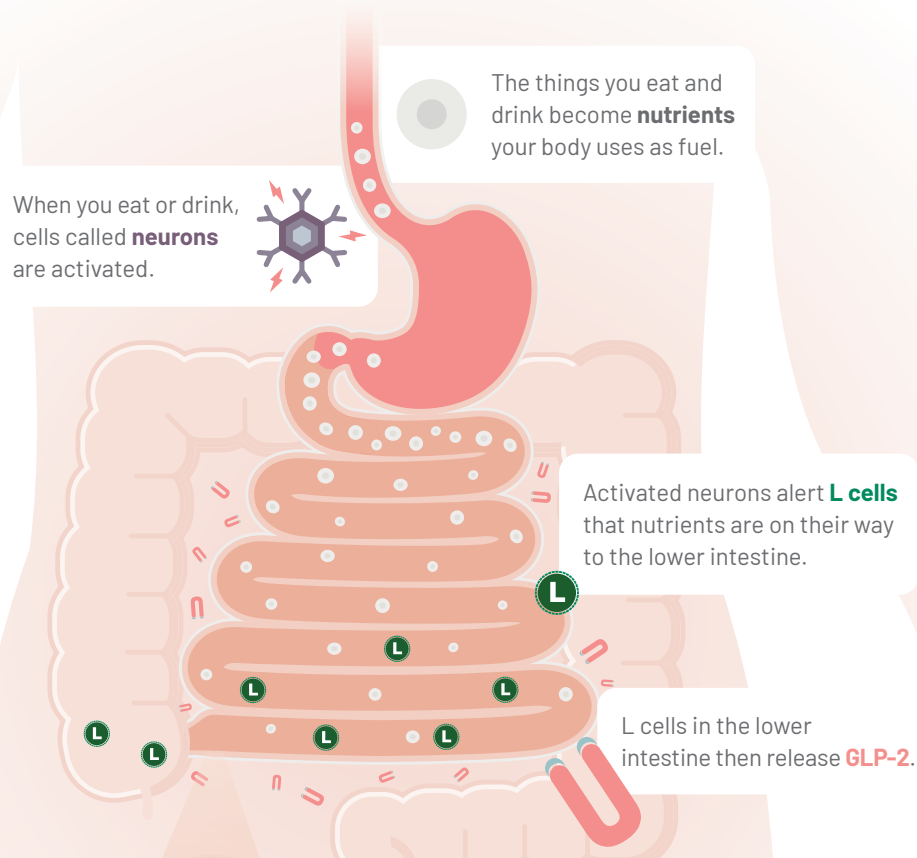
Long-term use of PS is not recommended because it can lead to infections and long-term complications

PS provides essential nutrition but does not help the intestine absorb nutrients on its own

Understanding the importance of the hormone GLP-2

GLP-2, short for glucagon-like peptide-2, is a hormone produced in the intestine that helps the body absorb nutrients and fluids

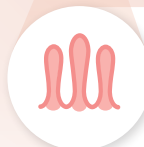
Hormones are chemical messengers that help your body in many different ways.



Key

 **L cells**

 **GLP-2**



GLP-2 increases the height of finger-like structures in the intestine called **villi**. Villi absorb nutrients that travel through the intestines. GLP-2 also increases blood flow in the intestine.

GLP-2 impacts the way your child's body absorbs nutrients and fluids

Children with short bowel syndrome (SBS) may not produce enough GLP-2 in their body

Without enough GLP-2, the nutrients and fluids your child's body absorbs from the things they eat and drink can be limited.

In people with SBS

Usually, people with SBS have **undergone surgery to remove parts of the intestine**. This may include portions containing L cells that produce GLP-2.

If those parts are removed, then **the body may not make enough GLP-2** to help the remaining intestine absorb nutrients and fluids.

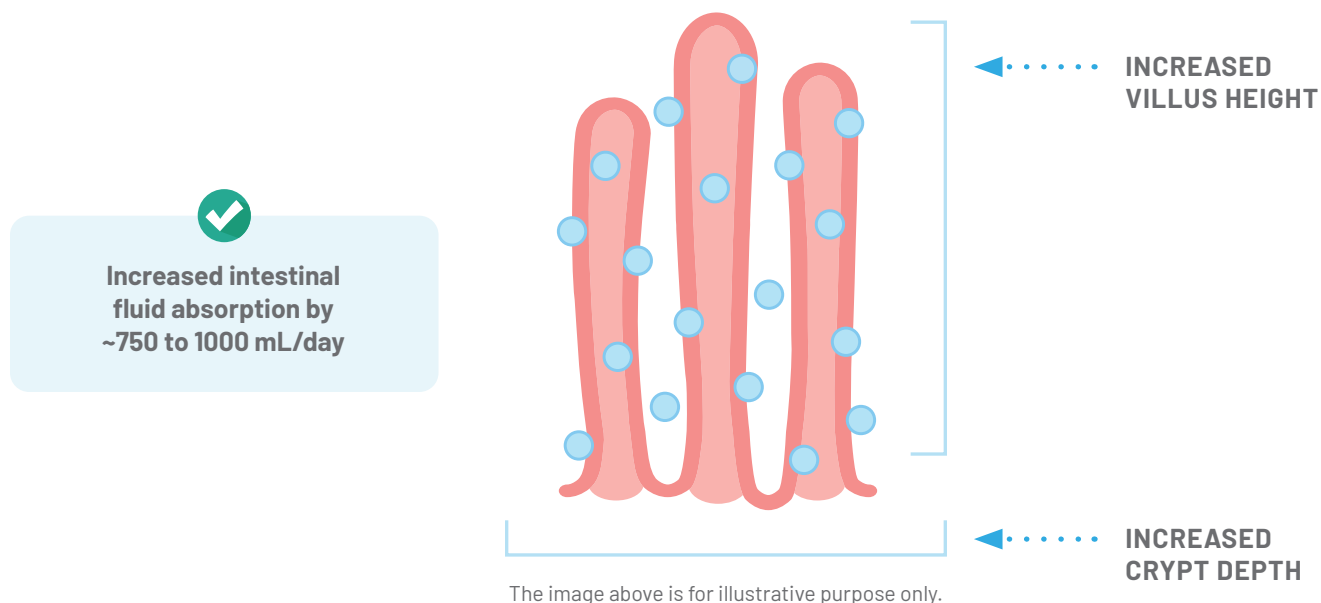
Increased height and depth of the villi can contribute to increased surface area, which may help the body absorb more nutrients.



Hypothetical illustration of a digestive tract following resection.

GATTEX is the first and only treatment that works like the GLP-2 the body normally makes on its own

In a study of adults, GATTEX was proven to help the remaining intestine absorb more fluid*†



*The ability of GATTEX to improve the amount of fluid absorbed by the intestines was studied in 17 adults with SBS. Participants in the study received GATTEX for 21 days. All the participants in this study knew they were taking GATTEX. They each took daily doses of either 0.03, 0.10, or 0.15 mg/kg by injection (0.6 to 3 times the recommended dose). The injections were administered under the skin in the stomach area (abdomen). All of the doses studied, except for the 0.03 mg/kg once-daily dose, resulted in enhanced absorption of fluid by the intestines—approximately 750 to 1000 mL per day—and increased the surface area of the intestines.

†The ability of GATTEX to improve intestinal absorption in children has not been investigated.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about GATTEX? (continued)

GATTEX may cause serious side effects, including:

Making abnormal cells grow faster

GATTEX can make abnormal cells that are already in the body grow faster. There is an increased risk that abnormal cells could become cancer. If your child gets cancer of the bowel (intestines), liver, gallbladder or pancreas while using GATTEX, the healthcare provider should stop GATTEX. If your child gets other types of cancers, you and the healthcare provider should discuss the risks and benefits of using GATTEX.

GATTEX may reduce the need for PS

In clinical studies, GATTEX was proven to help children with short bowel syndrome (SBS) on parenteral support (PS)



VOLUME

GATTEX **reduced the weekly volume of PS.**



TIME

People treated with GATTEX **achieved more time off of PS.**



FREEDOM

Over time, some people **achieved complete freedom from PS** with GATTEX.

In a 6-month study, 18 out of 26 children treated with GATTEX reduced weekly PS volume by 20% or more, 10 out of 26 achieved a reduction of at least 1 day off PS per week, and 3 out of 26 no longer needed PS.

Less time on PS could mean more time for your child to participate in:



Hobbies



School



Social
interaction



Sleep
and rest



Work

Examples of how some patients may spend their time with reduced PS requirements are for illustrative purposes only. Be sure to discuss your child's medical circumstances and activities with their doctor.

GATTEX was evaluated in a clinical study



Study design: In a 6-month study, **59 children aged 1 through 17** chose whether to receive GATTEX or standard of care (SOC).^{*} Children who were treated with GATTEX were subsequently randomized in a double-blind manner to receive either 0.025 mg/kg/day (n=24) or 0.05 mg/kg/day (n=26), while 9 children received SOC. Randomization to the GATTEX groups was stratified by age. All children were dependent on parenteral support (PS) prior to the study. The goal was to see if children treated with GATTEX achieved a reduction in weekly PS volume of at least 20% from baseline. The study also evaluated safety.

Patient baseline characteristics:

Demographics	People treated with GATTEX 0.05 mg/kg/day
Age	
1-11 years	92%
12-17 years	8%
Male	73%
Primary causes of SBS	
Gastroschisis	54%
Midgut volvulus	23%
Necrotizing enterocolitis	12%
Intestinal atresia	4%
Hirschsprung's disease	4%
Baseline characteristics	
Mean remaining small intestine length	28 cm
Mean PS infusion volume	60 mL/kg/day
Mean PS infusion time	7 days/week

GATTEX has been approved for use in children since 2019 and for adults since 2012



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Most children needed less volume of PS with GATTEX

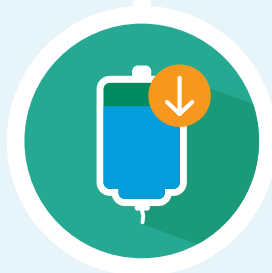
In a clinical study, children treated with GATTEX reduced parenteral support (PS) volume over time*

At 6 months with GATTEX

More than half

69% (18/26)

reduced their weekly volume of PS by 20% or more from baseline†



42% average reduction

(23 mL/day) in daily PS volume from baseline

Results are based on participant diary data.

*Results are presented for the 0.05 mg/kg/day dosage, which is the recommended dosage of GATTEX.

†Baseline average PS volume was 60 mL/kg/day.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about GATTEX? (continued)

GATTEX may cause serious side effects, including:

Polyps in the colon (large intestine)

Polyps are growths on the inside of the colon. The healthcare provider will check for blood in the stool before your child starts using GATTEX.

To keep using GATTEX, the healthcare provider should have your child's colon checked for new polyps at the end of 1 year of using GATTEX. If no polyp is found, the healthcare provider should check for polyps as needed and at least every 5 years and have any new polyps removed. If cancer is found in a polyp, the healthcare provider should stop GATTEX.



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Gattex[®]
(teduglutide) for injection

Children spent less time on PS with GATTEX

In a clinical study, GATTEX helped children achieve less time and fewer days on parenteral support (PS) each week*

At 6 months with GATTEX

38% (10/26) achieved
**at least 1 day
or more off of PS[†]**



**3 fewer hours
on average,
of PS per day[‡]**

*Results are presented for the 0.05 mg/kg/day dosage, which is the recommended dosage of GATTEX.

[†]7 days/week average baseline PS requirement for GATTEX 0.05 mg/kg/day dosage group.

[‡]11 hours/day average baseline PS requirement for GATTEX 0.05 mg/kg/day dosage group.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about GATTEX? (continued)

GATTEX may cause serious side effects, including:

Blockage of the bowel (intestines)

A bowel blockage keeps food, fluids, and gas from moving through the bowels in the normal way. Tell the healthcare provider right away if your child has any of these symptoms of a bowel or stomal blockage:

- trouble having a bowel movement or passing gas
- stomach area (abdomen) pain or swelling
- nausea
- vomiting
- swelling and blockage of a stoma opening, if your child has a stoma

If a blockage is found, the healthcare provider may temporarily stop GATTEX.



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Freedom from PS may be possible

Some children taking GATTEX achieved complete freedom from parenteral support (PS) after 6 months of treatment*



12% of children
(3/26) no longer needed PS

Not all children will fully wean off of PS.

*Results are presented for the 0.05 mg/kg/day dosage, which is the recommended dosage of GATTEX.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about GATTEX? (continued)

GATTEX may cause serious side effects, including:

Swelling (inflammation) or blockage of the gallbladder or pancreas

The healthcare provider will do tests to check your child's gallbladder and pancreas within 6 months before starting GATTEX and at least every 6 months while your child is using GATTEX. Tell the healthcare provider right away if your child gets:

- stomach area (abdomen) pain and tenderness
- nausea
- chills
- vomiting
- fever
- dark urine
- a change in stools
- yellowing of the skin or the whites of the eyes



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(teduglutide) for injection

What to expect when your child takes GATTEX

It may take time for GATTEX to work. The time it may take to see a reduction in parenteral support (PS) can vary

For the majority of children in the clinical study, GATTEX started to work within 6 months. For some children, it may take longer, or they may not respond at all.

Things to keep in mind during your child's treatment journey:



Track your child's experience and keep detailed notes that you can use in conversations with the doctor.



Check in with your child's doctor and talk openly about what your child is experiencing.



Your child should continue taking GATTEX as long as their doctor recommends.

Every child with SBS is unique, and your child's experience with GATTEX will be too

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about GATTEX? (continued)

GATTEX may cause serious side effects, including:

Fluid overload

The healthcare provider will check your child for too much fluid in the body. Too much fluid in the body may lead to heart failure, especially if your child has heart problems. Tell the healthcare provider if your child gets swelling in the feet and ankles, your child gains weight very quickly (water weight), or your child has trouble breathing.

GATTEX is administered once daily

GATTEX is an under-the-skin (subcutaneous) injection

There are a few things to know when taking GATTEX. These are not all the steps—be sure to refer to full **Instructions for Use**. Before your child starts GATTEX, you should receive administration training by a healthcare professional.



**Inject 1 time
each day at the
same time.**



**Inject in
1 of 3 areas:**
Stomach area,
either thigh, or
either upper arm.



**Use a different
injection site
each time.**

**GATTEX must be administered by an adult. Self-administration
by children or adolescents is not recommended**

Get to know more about GATTEX

Here are some easy ways to learn more about GATTEX and connect with the community:



SCAN THE QR CODE TO VISIT GATTEX.COM

With educational resources and discussion guides you can use with your child's doctor, [GATTEX.com](https://www.gatdex.com) can help you stay informed.



ATTEND A GATTEX SPEAKER PROGRAM

Learn more about GATTEX from a healthcare expert and hear from someone living with short bowel syndrome (SBS) who has experience with GATTEX. Call 1-855-575-3819 to learn more and register for a program.



LIKE US ON FACEBOOK

Find us on Facebook at [Facebook.com/GATTEX](https://www.facebook.com/GATTEX) to learn more and connect with others in the SBS community.

Other resources are available

Sometimes it's helpful to hear from others who are going through the same things as you and your child.

Listed are some dedicated nonprofit organizations that support people with SBS and their caregivers*:

THE CAREGIVER ACTION NETWORK (CAN)

The CAN's goal is to improve the quality of life for caregivers by offering free education, peer support, and resources. [caregiveraction.org](https://www.caregiveraction.org)

THE FAMILY CAREGIVER ALLIANCE

The Family Caregiver Alliance supports and sustains caregivers with national, state, and local programs and resources. [caregiver.org](https://www.caregiver.org)

THE NATIONAL ALLIANCE FOR CAREGIVING

The National Alliance for Caregiving focuses on advancing family caregiving through research and advocacy. [caregiving.org](https://www.caregiving.org)

THE NATIONAL ORGANIZATION OF RARE DISORDERS (NORD)

The NORD is a patient advocacy organization committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and service. [rarediseases.org](https://www.rarediseases.org)

THE OLEY FOUNDATION

The Oley Foundation helps those living with home intravenous nutrition and tube feeding. [oley.org](https://www.oley.org)

THE UNITED OSTOMY ASSOCIATIONS OF AMERICA (UOAA)

The UOAA supports, empowers, and advocates for people who have had or who will have ostomy or continent diversion surgery. [ostomy.org](https://www.ostomy.org)

*This information is provided as a resource and not intended to be an endorsement. Takeda is not responsible for the content of any website not owned by Takeda.

OnePath[®] is personalized product support



OnePath provides a range of product support services throughout your GATTEX treatment journey. From the moment you enroll your child in OnePath, a dedicated Patient Support Manager (PSM) will work with you one-on-one throughout their pathway to treatment and beyond. You'll also be introduced to an Onboarding & Access Specialist (OAS) in your area who will be one of your primary support persons as your child starts on their GATTEX therapy.

Your OnePath team is here to help you and your child:



Navigate the health insurance process



Find information about financial assistance options



Connect with reimbursement education



Coordinate with their specialty pharmacy



Set up one-on-one injection training with a Certified Nurse Educator



Stay informed about additional resources



Access GATTEX by working with their healthcare team as needed

For more information about OnePath and how to enroll, talk to your healthcare professional or visit [GATTEX.com/resources-and-support](https://www.gatdex.com/resources-and-support)

Important Safety Information

What is the most important information I should know about GATTEX?

GATTEX may cause serious side effects, including:

Making abnormal cells grow faster

GATTEX can make abnormal cells that are already in the body grow faster. There is an increased risk that abnormal cells could become cancer. If your child gets cancer of the bowel (intestines), liver, gallbladder or pancreas while using GATTEX, the healthcare provider should stop GATTEX. If your child gets other types of cancers, you and the healthcare provider should discuss the risks and benefits of using GATTEX.

Polyps in the colon (large intestine)

Polyps are growths on the inside of the colon. The healthcare provider will check for blood in the stool before your child starts using GATTEX.

To keep using GATTEX, the healthcare provider should have your child's colon checked for new polyps at the end of 1 year of using GATTEX. If no polyp is found, the healthcare provider should check for polyps as needed and at least every 5 years and have any new polyps removed. If cancer is found in a polyp, the healthcare provider should stop GATTEX.

Blockage of the bowel (intestines)

A bowel blockage keeps food, fluids, and gas from moving through the bowels in the normal way. Tell the healthcare provider right away if your child has any of these symptoms of a bowel or stomal blockage:

- trouble having a bowel movement or passing gas
- vomiting
- stomach area (abdomen) pain or swelling
- swelling and blockage of a stoma opening, if your child has a stoma
- nausea

If a blockage is found, the healthcare provider may temporarily stop GATTEX.

Swelling (inflammation) or blockage of the gallbladder or pancreas

The healthcare provider will do tests to check your child's gallbladder and pancreas within 6 months before starting GATTEX and at least every 6 months while your child is using GATTEX. Tell the healthcare provider right away if your child gets:

- stomach area (abdomen) pain and tenderness
- nausea
- chills
- vomiting
- fever
- dark urine
- a change in stools
- yellowing of the skin or whites of the eyes

Fluid overload

The healthcare provider will check your child for too much fluid in the body. Too much fluid in the body may lead to heart failure, especially

if your child has heart problems. Tell the healthcare provider if your child gets swelling in the feet and ankles, your child gains weight very quickly (water weight), or your child has trouble breathing.

The most common side effects of GATTEX in adults include:

- stomach area (abdomen) pain or swelling
- vomiting
- nausea
- swelling of the hands or feet
- cold or flu symptoms
- allergic reactions
- skin reaction where the injection was given

The side effects of GATTEX in children and adolescents are similar to those seen in adults. Tell the healthcare provider if your child has any side effect that bothers you or your child or that does not go away.

What should I tell the healthcare provider before my child uses GATTEX?

Tell the healthcare provider about all your child's medical conditions, including if your child:

- has cancer or a history of cancer
- has or had polyps anywhere in the bowel (intestines) or rectum
- has heart problems
- has high blood pressure
- has problems with the gallbladder, pancreas, kidneys
- is pregnant or planning to become pregnant. It is not known if GATTEX will harm an unborn baby. Tell the healthcare provider right away if your child becomes pregnant while using GATTEX.
- is breastfeeding or plans to breastfeed. It is not known if GATTEX passes into breast milk. Your child should not breastfeed during treatment with GATTEX. Talk to the healthcare provider about the best way to feed a baby while using GATTEX.

Tell the healthcare providers about all the medicines your child takes, including prescription or over-the-counter medicines, vitamins, and herbal supplements. Using GATTEX with certain other medicines may affect each other causing side effects. Other healthcare providers may need to change the dose of any oral medicines (medicines taken by mouth) your child takes while using GATTEX. Tell the healthcare provider who gives your child GATTEX if your child will be taking a new oral medicine.

Call the doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For additional Important Safety Information, click for full [Prescribing Information and Medication Guide](#), and discuss any questions with your child's doctor.



DISCOVER WHAT FREEDOM FROM PARENTERAL SUPPORT (PS) COULD LOOK LIKE

Individual results may vary



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Learn more at [GATTEX.com](https://www.gattex.com)

What is GATTEX?

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