

Website for patients who use Dupixent®



<https://www.support-allergy.com>

It provides product information on Dupixent® and other useful information.



Website for patients with allergic diseases in Japan



アレルギー-i

<https://www.allergy-i.jp>

This is an allergy information site for patients who aim to maintain their usual performance while dealing with allergies.



## Learn more about the Dupixent® 300 mg pen the easy way with videos!

For patients who use the Dupixent® 300 mg pen, we have prepared videos to help you learn more.

Please scan the QR code below.



How Dupixent® works



Self-injection procedure (syringe)



Self-injection procedure (pen)



Things you should know about the medical expense subsidy systems

For questions about how to operate Dupixent® injectors or the medical fee support system, please contact the Dupixent® Consultation Office.

## Dupixent® Consultation Office

Toll-free number

**0120-50-4970**

An expert staff member will take your call

**1** Questions about how to operate injectors  
**24 hours a day, 365 days a year**

**2** Questions about the medical fee support system  
**Mon. to Sat. 9:00 to 21:00**  
(closed Sun. and holiday)

\* Service **2** offers a rough estimate of medical fees based on the medical fee support system; we cannot respond to queries about medical practices or the details of treatment. Furthermore, as the medical fee support system varies according to municipality, please contact the city, town, or village in which you live.

\* Dupixent® Consultation Office records calls for the purpose of improving our customer service. Thank you in advance for your understanding.

9th Edition

For chronic rhinosinusitis patients with nasal polyps who use

# DUPIXENT®

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sanofi | REGENERON

# Your treatment goal

Chronic rhinosinusitis is a chronic disease that causes inflammation of the sinuses.

Some types of chronic rhinosinusitis are difficult to treat and may recur repeatedly even with conventional drug therapy or surgery.

**Dupixent®** is a new type of drug that works by a different mechanism than conventional drugs.

Even if your symptoms were not well controlled with your previous medication, you can expect to improve your symptoms and maintain control with Dupixent®.

This brochure explains the characteristics, usage, and side effects of **Dupixent®**. If you have any questions or concerns, please do not hesitate to consult your physician, nurse, or pharmacist.

The goal of treatment for chronic rhinosinusitis is to **"maintain control of nasal symptoms and live your life like a healthy person"**. What is your treatment goal? (What do you want to do after your nasal symptoms subside?)

Write your treatment goal here.

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Examples of treatment goals

Sleep well at night



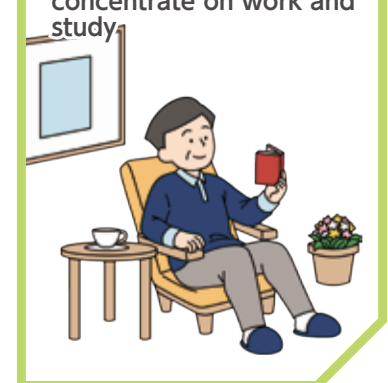
Enjoy the sense of smell



Enjoy eating



Have the ability to concentrate on work and study



# Symptoms and disease burden (difficulties in your daily life) associated with chronic rhinosinusitis with nasal polyps

## ▶▶ Nasal congestion



- I can't sleep well. Severe insomnia can lead to mental instability.



- I hesitate to travel now because I was told that my snoring is noisy.



- Nasal congestion and lack of sleep make it hard to concentrate. Driving is dangerous.



- Asthma attacks or choking on phlegm makes it so hard to breathe that I'm afraid I will suffocate.



- Severe nasal congestion makes me lose my breath right away when exercising. I can't refresh myself with tennis, so I tend to feel low.



- Going out makes me tired, so I tend to spend my weekends at home.

## ▶▶ I can't smell anything (smell disorder)



- I can't smell the aroma of foods, so eating is no fun.



- I can't smell gas leaks or know if food has gone bad.



- I am concerned about my body odor and whether it is bothering others.



- I neglect to change my elderly mother's adult diaper because I've lost my sense of smell.



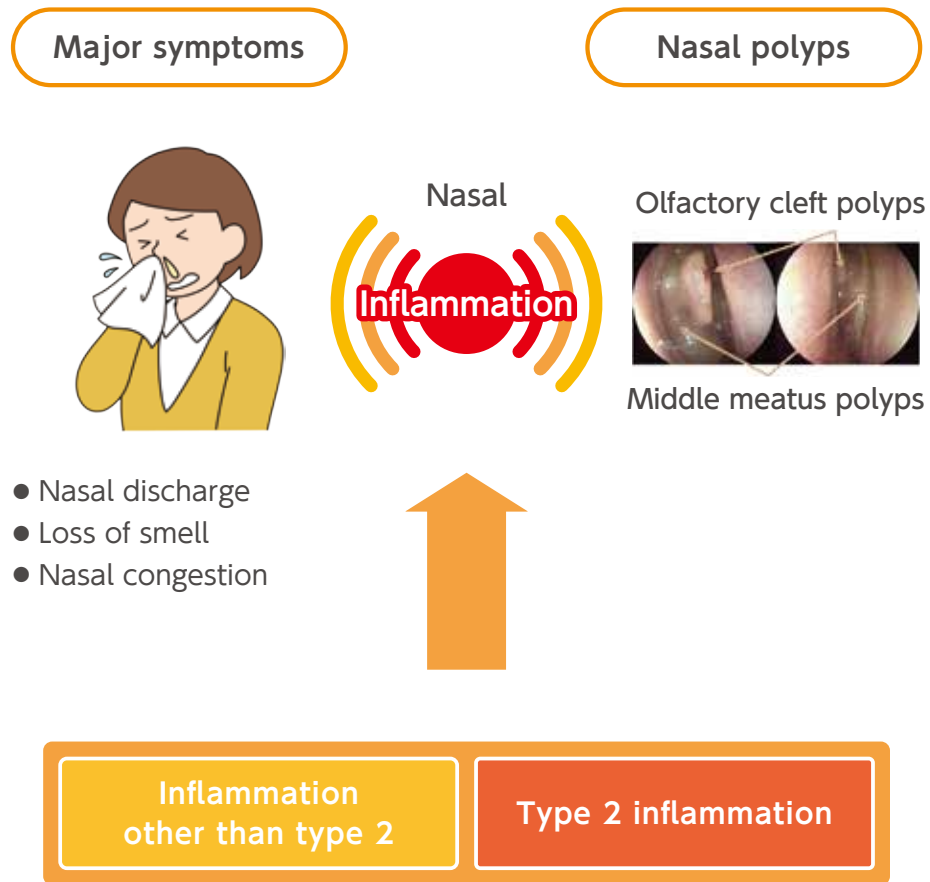
- Wine was my hobby, but now that I can't smell the bouquet of my favorite wines, some of the fun has gone out of daily life.



- I feel isolated because my inability to enjoy the aroma of food has reduced the number of times I go out for drinks with colleagues or dine together with business partners.

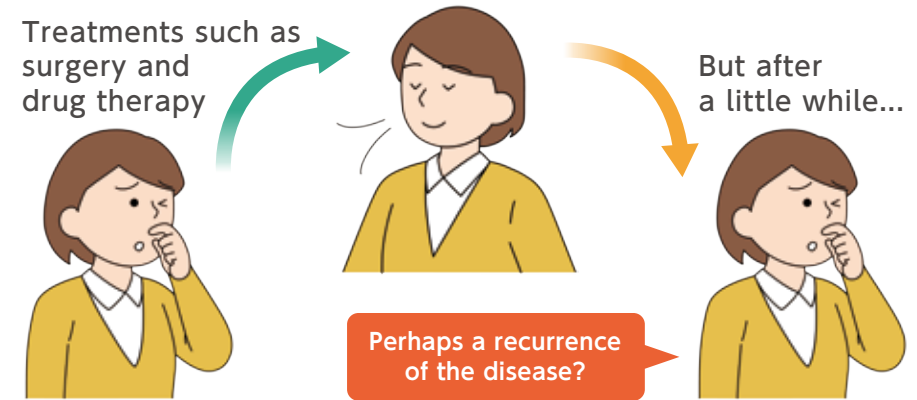
# Inflammation and type of chronic rhinosinusitis with nasal polyps

When inflammation in the nose (mainly type 2 inflammation) persists, symptoms of chronic rhinosinusitis appear. Also, nasal polyps develop in the nose and become large.



# Tendency of nasal polyps to recur in chronic rhinosinusitis with nasal polyps

In chronic rhinosinusitis with nasal polyps, the nasal polyps may recur despite surgery or treatment with drugs.



JESREC study: data based on follow-up for approx. 3 years (22.6 months) Among patients with eosinophilic rhinosinusitis, 23.4% to 51.8% had relapse after surgery for chronic rhinosinusitis with nasal polyps.

Types of chronic rhinosinusitis	Nasal polyp recurrence rate (about 3 years of follow-up)	
Non-eosinophilic rhinosinusitis	12.7%	
Eosinophilic rhinosinusitis (mild)	23.4%	
Eosinophilic rhinosinusitis (moderate)	31.1%	
Eosinophilic rhinosinusitis (severe)	51.8%	

Fujieda S, et al: Nippon Jibiinkoka Gakkai kaiho. 2015; 118: 728-735  
 Japan Intractable Diseases Information Center: Eosinophilic rhinosinusitis (designated intractable disease 306)  
<https://www.nanbyou.or.jp/entry/4538> [accessed January 26, 2023]

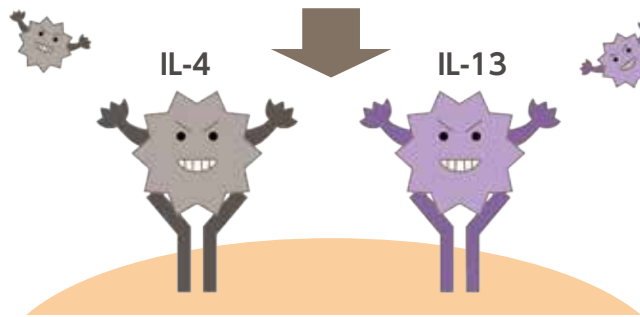
# What is happening in your nose and sinuses

Annoying nasal symptoms such as nasal congestion, nasal discharge, and smell disorder.

These symptoms are caused by "inflammation" that occurs in your nose and paranasal sinuses. The substances IL-4 (interleukin-4) and IL-13 (interleukin-13), which are produced by immune cells, are deeply involved in inflammation.

## What is happening in chronic rhinosinusitis

Infections Living environment Allergies, etc.



Symptoms of rhinosinusitis



- Nasal congestion
- Loss of smell
- Sticky nasal discharge

Nasal polyps form

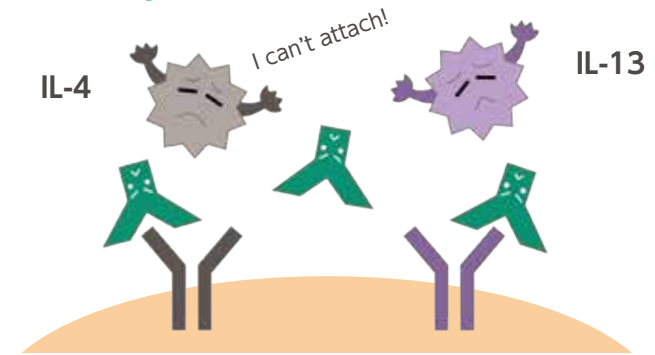


# How Dupixent® works

Dupixent® suppresses nasal and sinus inflammation by inhibiting the actions of IL-4 and IL-13.

Reducing inflammation is expected to reduce nasal polyps and improve nasal symptoms such as nasal congestion and loss of smell.

## You can expect treatment with Dupixent® to have the following effects:



Improves symptoms of rhinosinusitis



- Airflow in the nose improves
- Sense of smell improves
- Symptoms of nasal discharge are alleviated

Shrinks nasal polyps



# Effects of Dupixent<sup>®</sup>

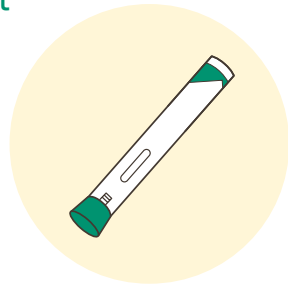
Dupixent<sup>®</sup> suppresses the functions of **IL-4 and IL-13** which play a **central role** in inflammation and the symptoms of chronic rhinosinusitis.

Even in patients who did not have good control with conventional treatment, Dupixent<sup>®</sup> can be expected to inhibit inflammation to **improve symptoms of rhinosinusitis and shrink nasal polyps**.

Continued treatment with Dupixent<sup>®</sup> can also be expected to **maintain a good condition for a long period of time**.

## Beneficial effects you can expect from Dupixent<sup>®</sup>

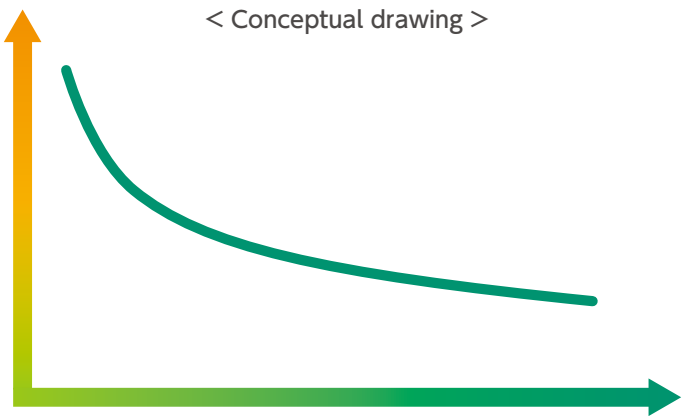
- Makes nasal polyps smaller
- Improves nasal congestion
- Improves loss of smell
- Improves nasal discharge
- Long-term suppression of symptoms, etc.



Large nasal polyps, severe symptoms



< Conceptual drawing >



Small nasal polyps, mild symptoms

Duration of treatment with Dupixent<sup>®</sup>

# Patients who can be treated with Dupixent<sup>®</sup>

## Patients who can receive Dupixent<sup>®</sup>

Dupixent<sup>®</sup> can be used by patients with chronic rhinosinusitis with nasal polyps whose symptoms do not improve even with drug therapy such as systemic steroids, or who cannot maintain a long-term improvement or have relapsed after surgery.



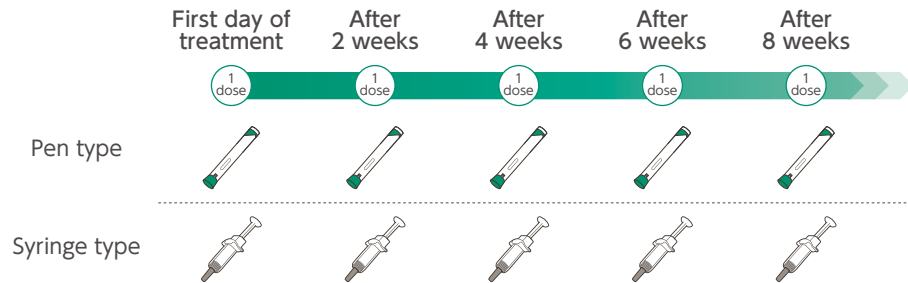
## Patients who require careful administration

- Patients with parasitic infection
- Patients who are scheduled to receive live vaccines
- Women who are pregnant or could be pregnant, lactating women
- Elderly patients
- Patients with asthma or other allergic conditions

# How to proceed with treatment with Dupixent®

## » Dosing schedule

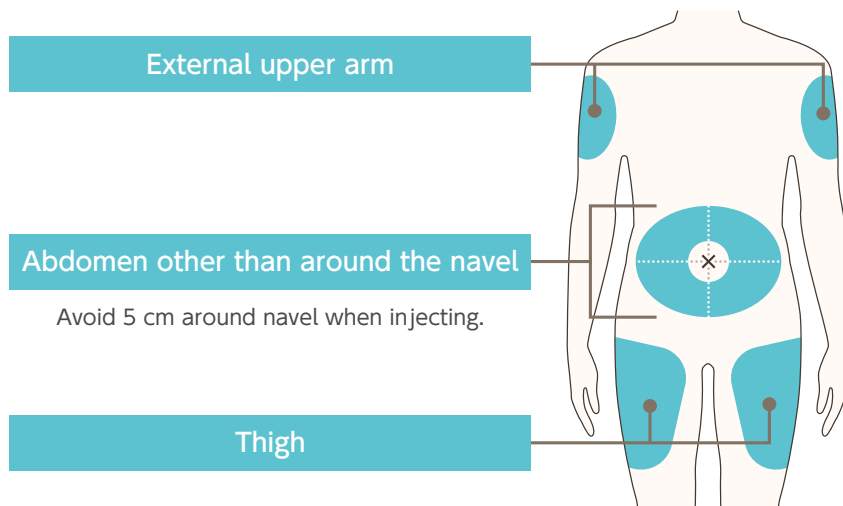
Dupixent® is given by subcutaneous injection once every 2 weeks. After the symptoms become stable, the dosing frequency may be changed to every 4 weeks at the discretion of your attending physician. Be sure to follow your doctor's instructions.



After the symptoms become stable, the drug will be administered at 2-week intervals or 4-week intervals at the discretion of the physician.

## » Administration site

There are three suitable injection sites:



\*For self-injection, use abdomen (except for around navel) or thigh.

## » You can inject Dupixent® yourself

“Self-injection” is possible with Dupixent®. This means that you inject it yourself under the doctor's supervision.



## » Benefits of self-injection

- Treatment can better fit your lifestyle, saving the time and burden of hospital visits.
- Flexibility in visit dates expands your range of activities in work, travel, etc.



## What do I do about my existing treatment?

If you had other treatment or care prior to receiving Dupixent®, do not stop it at your own discretion. Consult your doctor and follow instructions.



Administration of Dupixent® can cause side effects. If you experience side effects, tell your doctor, nurse, or pharmacist immediately.

## Major known side effects

### Injection site reaction

This is a reaction in which pain, redness, swelling, itching, or bleeding occurs in the part you injected (arm, abdomen, thigh).



Redness, swelling



Itching

## Side effects that are unlikely but require special attention

### Symptoms due to anaphylactic reaction

This is a hypersensitivity reaction that generally occurs immediately after administration of medication. It has the following symptoms.

- Dizziness, lightheadedness, dizziness on standing up, lassitude, decreased consciousness
- Respiratory distress, wheezing when you breathe
- Abdominal pain, nausea, vomiting
- Itching, redness, swelling of skin, systemic rash
- Swollen lips or tongue, etc.



Japanese Society of Allergology: Anaphylaxis Guidelines (1st Edition), Medical Review Co., Ltd., 2014, p. 11

### Symptoms due to increase in eosinophil count

Dupixent® may cause a temporary increase in blood eosinophil count in some patients. A slight increase in eosinophil count alone is not usually associated with symptoms, but the following symptoms may occasionally occur:

- Cough, fever, lassitude, shortness of breath, respiratory distress, wheezing when you breathe, bloody sputum (phlegm mixed with blood)
- Palpitations, difficulty breathing
- Rash, swelling
- Hand and foot numbness, paralysis (difficulty moving), etc.





# Precautions for patients with asthma or other allergic conditions

Dupixent® can cause changes in the symptoms of asthma or other allergic diseases.

If you have the complication of allergic disease such as asthma, atopic dermatitis or urticaria, be sure to tell the doctor who is treating you for chronic rhinosinusitis the name of the complication or therapeutic drug. Also, tell the doctor treating you for the other condition that you are using Dupixent®.

Don't reduce or stop medication for asthma, atopic dermatitis, or urticaria at your own discretion. Be sure to follow your doctor's instructions.

## Pocket card for patients with asthma or other allergic diseases

### Tell the doctor treating you for chronic rhinosinusitis

I use inhalants for the treatment of asthma.



Tell the doctor about your use of medications to treat asthma and other allergic conditions

### Tell the doctor treating you for asthma or other allergic condition

I have started using Dupixent® for the treatment of chronic rhinosinusitis.



Tell the doctor that you are using Dupixent®

Present the pocket card shown on page 17

# Keep a "treatment diary"

If you have any symptoms on the day you inject, record them in your treatment diary and show it to your doctor when you visit the hospital.

**Example of entry**

Rate your symptoms on the day of injection as follows:  
 0 = No symptoms  
 1 = Mild (slight symptoms that you can ignore)  
 2 = Moderate (bothersome but tolerable)  
 3 = Severe (interferes with daily life, intolerable)  
 Circle the one that describes your symptoms.

Record any other concerns you may have

Day of injection 4 / 1	Nasal congestion 0 1 2 <b>3</b>	Can't smell anything 0 1 2 <b>3</b>	Nasal discharge 0 1 <b>2</b> 3	Other <b>Redness at the injection site</b>
How bothersome are your rhinosinusitis symptoms? 0 _____ 10				

Mark the rating scale with a vertical line showing how much you are bothered by rhinosinusitis symptoms (0 = Can ignore them, 10 = The most bothersome symptoms imaginable)

Day of injection /	Nasal congestion 0 1 2 3	Can't smell anything 0 1 2 3	Nasal discharge 0 1 2 3	Other
How bothersome are your rhinosinusitis symptoms? 0 _____ 10				

Day of injection /	Nasal congestion 0 1 2 3	Can't smell anything 0 1 2 3	Nasal discharge 0 1 2 3	Other
How bothersome are your rhinosinusitis symptoms? 0 _____ 10				

Day of injection /	Nasal congestion 0 1 2 3	Can't smell anything 0 1 2 3	Nasal discharge 0 1 2 3	Other
How bothersome are your rhinosinusitis symptoms? 0 _____ 10				

Day of injection /	Nasal congestion 0 1 2 3	Can't smell anything 0 1 2 3	Nasal discharge 0 1 2 3	Other
How bothersome are your rhinosinusitis symptoms? 0 _____ 10				

Day of injection /	Nasal congestion 0 1 2 3	Can't smell anything 0 1 2 3	Nasal discharge 0 1 2 3	Other
How bothersome are your rhinosinusitis symptoms? 0 _____ 10				

# Medical insurance system

In Japan, everyone is required to enroll in public health insurance (universal health insurance system).

This system bears a part of the medical expenses when medical insurance subscribers and their family members (dependents) need medical care. The type of public medical insurance that you have to enroll in varies depending on your job type, age, etc.

## Public medical insurance

- Union-managed health insurance (health insurance union)
- Japan Health Insurance Association (Kempo Association)
- Seamen's Insurance
- Mutual Aid Association
- National Health Insurance
- National Health Insurance Union
- Medical system for the elderly aged 75 or over

○ Health insurance card      ○ (Insured)  
 Date of issuance: \_\_\_\_\_  
(YYYY/MM/DD)

Insured's Code 000 No. 0000

Name ○ ○ ○ Sex ○

Date of birth \_\_\_\_\_  
(YYYY/MM/DD)

qualification date \_\_\_\_\_  
(YYYY/MM/DD)

Insurer's address 〒000-0000 ○○○○○○

Insurer number 00000000

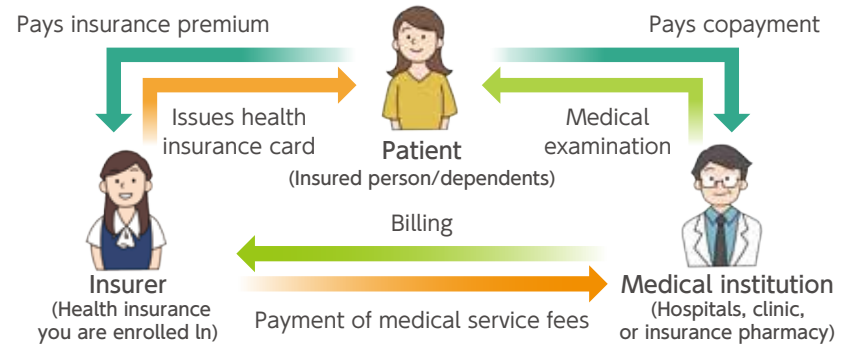
Insurer name ○○○○○○○○

**Various procedures and contact information differ depending on the medical insurance. Please check with the insurer indicated on your health insurance card.**

\*In this brochure, "medical insurance" refers to public medical insurance.

# Medical expenses and health insurance

## Image of medical insurance system



## Copayment ratio for medical expenses\*



\*Some municipalities have their own medical subsidy system.  
 \*\*Persons other than active duty level income earners with income above a certain level aged 75 years or older will pay 20%.

## Approximate cost of Dupixent®

For the latest costs involved, please ask at your hospital.  
 You can also check it on the following website  
 (Only available in Japanese).

Approximate cost of Dupixent®



# Medical expense subsidy systems

The national government, local governments, etc. have established medical expense subsidy systems to reduce the burden of medical expenses for patients.

By using these systems, you may be able to receive a subsidy if your medical expenses are high or you are diagnosed with a designated intractable disease.

## High-cost medical care benefit system (→Pages 22-31)

This is a system to reduce the patient's copayment to a certain amount when the monthly medical expenses are high. The amount exceeding the upper limit of your copayment will be paid by your medical insurance.

## Medical expense subsidy system for designated intractable diseases (→Pages 32-37)

If a patient is diagnosed with a government-designated intractable disease, the medical expenses for the treatment of the disease can be subsidized. Because eosinophilic rhinosinusitis is a designated intractable disease, patients receiving Dupixent® who have been diagnosed with eosinophilic rhinosinusitis may be able to receive medical subsidies.

## Other medical expense subsidy systems (→Pages 38-39)

You may also be able to receive medical subsidies through a health insurance union or local government.

# High-cost medical care benefit system

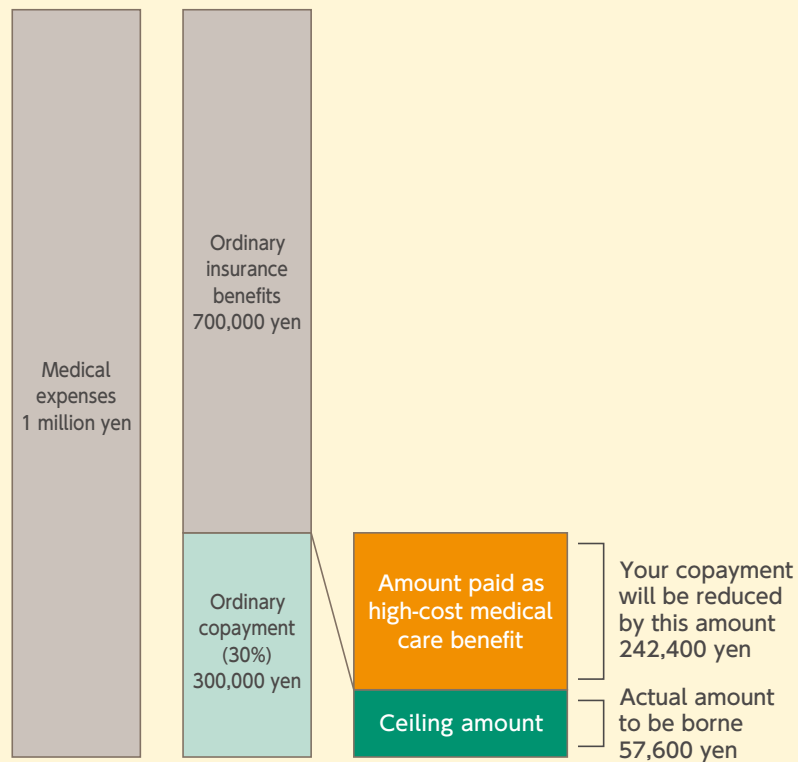
## High-cost medical care benefit system

In this system, if the amount to be paid at the payment counter of a medical institution (copayment amount) exceeds a certain amount in a month (1st to last day of the month), the copayment can be reduced to a certain amount (ceiling amount).

Examples

### When medical expenses in a month (100%) have totaled 1 million yen

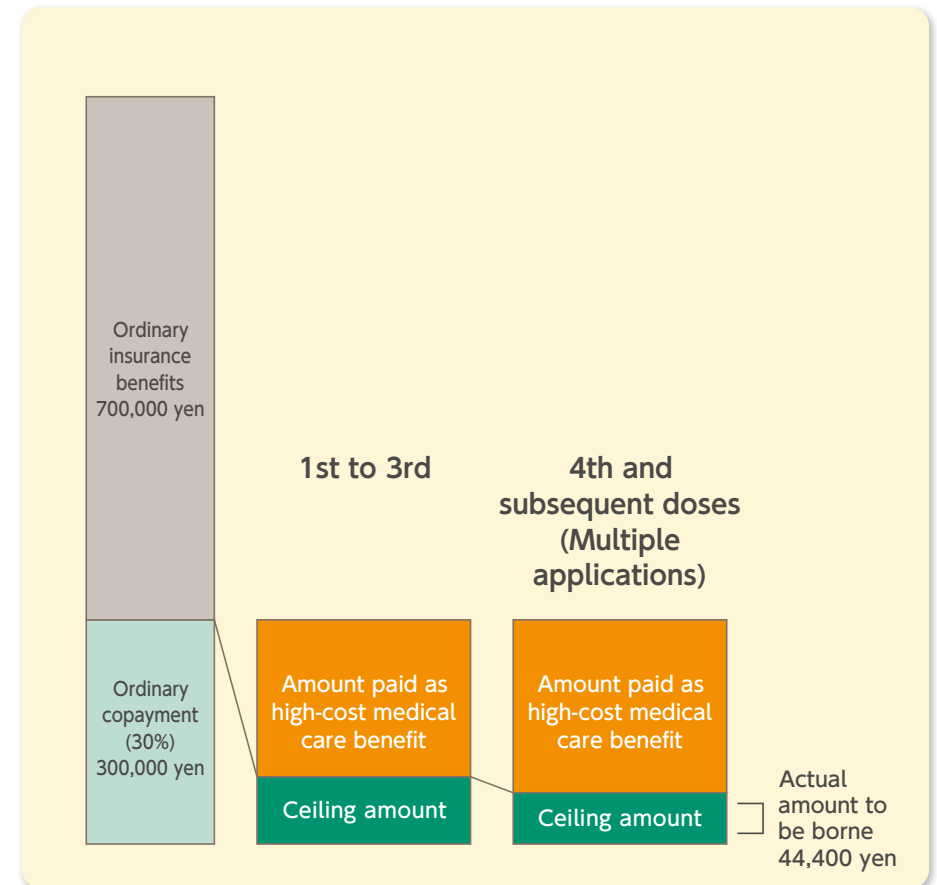
If you are 69 years old or younger and have application category "D" (For more information, see page 24)



## System for "multiple applications"

If you need to continuously receive expensive medical care, there is a system by which the upper limit of your out-of-pocket expenses ("ceiling amount") can be further reduced.

If you have received 3 or more applications of the high-cost medical care benefit system within the past 12 months (referred to as "multiple applications"), the ceiling amount for the 4th and subsequent months will be further reduced.



# High-cost medical care benefit system (ceiling amount)

## Ceiling amount (monthly)

The ceiling amount for your monthly out-of-pocket expenses depends on your age and household income.

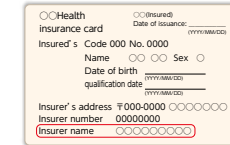
\*Please contact your health insurer (health insurance union, etc.) to determine which coverage category you have.



### Ceiling for people aged 69 years or under

Application category Approximate income		Maximum amount per month (per household)	Multiple applications
A	<b>Annual income &gt; 11.6 million yen</b> Non-national health insurance: Standard monthly remuneration 830,000 yen or more National Health Insurance: Former proviso income Over 9.01 million yen	252,600 yen + (Medical expenses – 842,000 yen) × 1%	140,100 yen
B	<b>Annual income approximately 7.7 million to 11.6 million yen</b> Non-national health insurance: Standard monthly remuneration 530,000 to 790,000 yen National Health Insurance: Former proviso income 6 million to 9.01 million yen	167,400 yen + (Medical expenses – 558,000 yen) × 1%	93,000 yen
C	<b>Annual income approximately 3.7 million to 7.7 million yen</b> Non-national health insurance: Standard monthly remuneration 280,000 to 500,000 yen National Health Insurance: Former proviso income 2.1 million to 6 million yen	80,100 yen + (Medical expenses – 267,000 yen) × 1%	44,400 yen
D	<b>Annual income up to approximately 3.7 million yen</b> Non-national health insurance: Standard monthly remuneration 260,000 yen or less National Health Insurance: Former proviso income 2.1 million yen or less	57,600 yen	44,400 yen
E	<b>Person exempted from residence tax</b>	35,400 yen	24,600 yen

For details of the contents and procedures of the high-cost medical care benefit system, please check with the insurer indicated on your health insurance card (Health Insurance Union, Japan Health Insurance Association, etc. [If you are subscribed to the National Health Insurance, municipality]).



### Ceiling for people aged 70 years or older

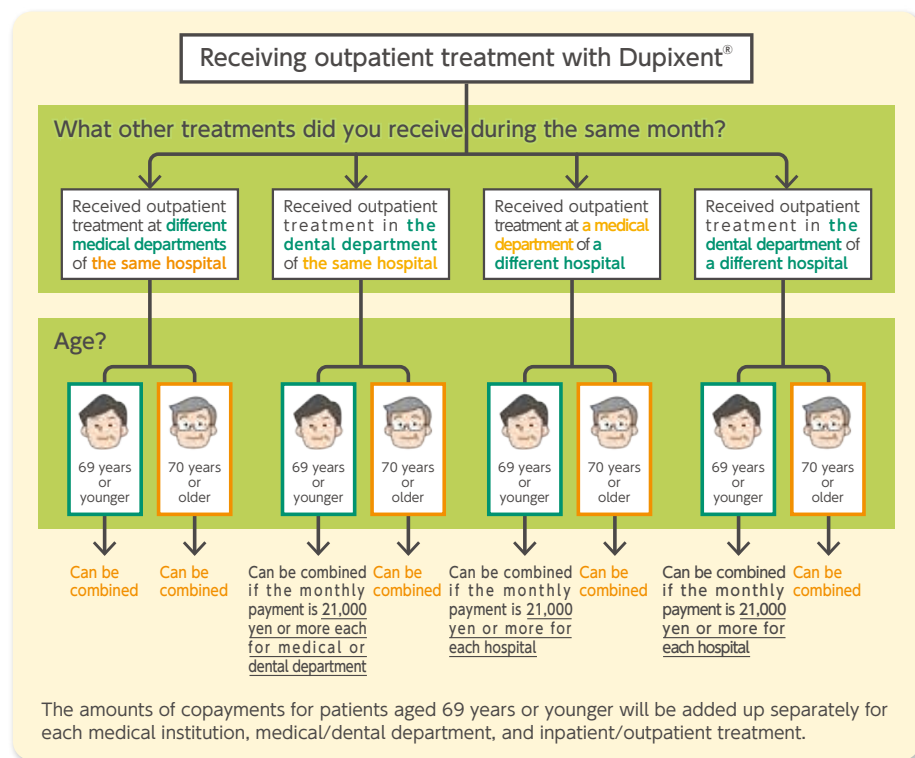
Application category	Approximate income	Maximum amount per month (per household)		Multiple applications
		In case of outpatient only (individual)		
Active income earner level	III. Annual income of 11.6 million yen or more Standard monthly remuneration 830,000 yen or more Taxable income of 6.9 million yen or more	252,600 yen + (Medical expenses – 842,000 yen) × 1%		140,100 yen
	II. Annual income approximately of 7.7 million to 11.6 million yen Standard monthly remuneration: 530,000 yen or more Taxable income of 3.8 million yen or more	167,400 yen + (Medical expenses – 558,000 yen) × 1%		93,000 yen
	I. Annual income of approximately 3.7 million to 7.7 million yen Standard monthly remuneration: 280,000 yen or more Taxable income of 1.45 million yen or more	80,100 yen + (Medical expenses – 267,000 yen) × 1%		44,400 yen
General	<b>Annual income: 1.56 million to approximately 3.7 million yen</b> Standard monthly remuneration 260,000 yen or less Taxable income of less than 1.45 million yen	18,000 yen  (Annual cap) 144,000 yen)	57,600 yen	44,400 yen
Exemption from residence tax, etc.	II. Households exempted from residence tax	8,000 yen	24,600 yen	Not applicable
	I. Households exempted from residence tax (Pension income ≤ 800,000 yen)		15,000 yen	

# High-cost medical care benefit system (medical expenses covered)

## Medical expenses covered by the high-cost medical care benefit system

Even if the ceiling amount is not exceeded by copayments (including out-of-hospital prescription fees) at one medical institution, etc., they can be combined with copayments made in the same month at another medical institution, etc. (If the patient is 69 years old or younger, they need to equal or exceed 21,000 yen). If the total amount exceeds the ceiling amount, the high-cost medical care benefit system will apply.

### If combined



Please see here for details about the system.  
 Ministry of Health, Labour and Welfare  
 "For Patients Using the High-Cost Medical Care Benefit System"

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryuu/iryuuohoken/juuyou/kougakuiryou/index.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/iryuuohoken/juuyou/kougakuiryou/index.html)

## Total for household

You can apply by adding up the amounts of copayments for family members who have the same medical insurance (same household).

**Examples** Example of calculation of reimbursement  
 If you are 69 years old or younger and have application category "D" (See page 24)

**Father** Amount of copayment paid per month = 36,000 yen (Medical expenses + drug expenses = 120,000 yen)

**Child** Amount of copayment paid in same month as father's copayment = 24,000 yen (Medical expenses + drug expenses = 80,000 yen)

When copayments for father and child are added up = 36,000 yen + 24,000 yen = 60,000 yen

If the medical expenses of father and child (medical expenses + drug expenses) are combined = 120,000 yen + 80,000 yen = 200,000 yen

The ceiling amount for copayments for this household is **57,600 yen**

**Amount of reimbursement = Amount of copayments made at payment counter - Ceiling amount**  
**2,400 yen = 60,000 yen - 57,600 yen**

For both the insured and family members, there is a limit to the combined medical expenses for patients aged 69 or younger. (Can be combined only when the monthly amount of copayments (30%) for 1 medical institution is 21,000 yen or more. Medical expenses for medical institutions at which the amount of copayments totals less than 21,000 yen cannot be combined.)

\*If you are 70 years old or older, you can combine your copayments regardless of the amount.

# High-cost medical care benefit system (how to apply)



## How to apply for the high-cost medical care benefit system

Ask your insurer to issue an "Eligibility Certificate for Ceiling-Amount Application" in advance and present it at the payment counter of the medical institution or pharmacy at the time of your visit.

- When the "Eligibility Certificate for Ceiling-Amount Application" is presented at the payment counter, the amount of copayment paid at the payment counter can be reduced to the ceiling amount (Refer to pages 24-25).
- You must apply to the insurer (health insurance union in which you are enrolled, etc.) in advance for the "Eligibility Certificate for Ceiling-Amount Application". Please contact the number printed on your health insurance card as soon as possible because the procedures and the period until delivery vary depending on the insurer.
- For people 70 years or older with an application category of "Active income earner level III" or "General" (See page 25), it is not necessary to present the "Eligibility Certificate for Ceiling-Amount Application". Therefore, you do not need to receive a "Eligibility Certificate for Ceiling-Amount Application" in advance.

If the "Eligibility Certificate for Ceiling-Amount Application" cannot be presented at the time of the medical examination, you may apply for the refund for the amount paid in excess of the ceiling amount after the usual medical expenses (10 to 30%) are paid.

- If the "Eligibility Certificate for Ceiling-Amount Application" cannot be presented at the payment counter, the usual medical expenses (10 to 30%) need to be paid once.
- At a later date, you must follow the procedure for claiming a reimbursement for the amount of money paid in excess of the ceiling amount to the health insurance union, etc. in which you are enrolled. At that time, you may be asked to attach receipts received at hospitals, etc., so keep them in a safe place.
- The application period for reimbursement of high-cost medical expenses will be 2 years from the month following the month in which you received medical care.

## Simulation for high-cost medical care expenses is available on our website.

The amount of high-cost medical care benefit can be calculated easily based on the monthly copayment and annual income.

Please scan the QR code to the right.



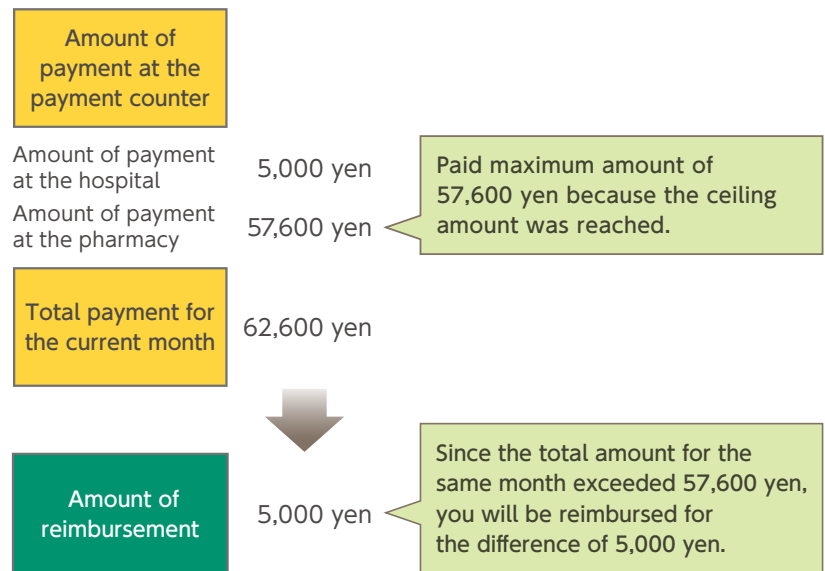
## If you receive a drug at a dispensing pharmacy

If you receive a drug at a dispensing pharmacy, you need to follow the procedure for reimbursement at a later date even if you have an "Eligibility Certificate for Ceiling-Amount Application."

- If you receive your medicine at a dispensing pharmacy, you can apply for the high-cost medical care benefit system by adding up the amount paid at the hospital and the pharmacy. However, hospital and pharmacy payments are not automatically combined, and you will have to pay up to the maximum copayment amount at both the hospital and pharmacy.
- At a later date, you can receive reimbursement for amounts paid in excess of the upper limit by following the procedure of the health insurance union, etc. in which you are enrolled.

Examples

If you are 69 years old or younger, the application category is "D", and the ceiling amount for your copayments for the month is 57,600 yen



# High-cost medical care benefit system – Procedures for use

## 1 Before visit

Contact the insurer indicated on your health insurance card (See page 19) and tell them that you want to use the high-cost medical care benefit system, check the following points, and follow the procedure for receiving a "Eligibility Certificate for Ceiling-Amount Application".\*



<input checked="" type="checkbox"/> Check with insurer	Entry column
<input type="checkbox"/> Application category and monthly ceiling amount ➡ Pages 24 - 25	Ceiling amount: _____ yen/month [In the case of 4th and subsequent times (multiple applications): _____ yen/month]
<input type="checkbox"/> Presence or absence of "additional benefit" ➡ Page 38	( Yes / No ) [If yes: (maximum: _____ yen/month)]
<input type="checkbox"/> Application method for "Eligibility Certificate for Ceiling-Amount Application" ➡ Page 28	Items to be attached and presented at the time of application ( )
<input type="checkbox"/> Period until the "Eligibility Certificate for Ceiling-Amount Application" arrives (Approximate)	

## 2 At the time of visit

Present the "Eligibility Certificate for Ceiling-Amount Application" at the payment counter of the medical institution, etc. with your health insurance card.\*

## 3 After visit

In the following cases, you might have paid medical expenses beyond the monthly ceiling amount at the hospital. By applying to your insurer, you can be reimbursed for any expenses you have paid that exceed the ceiling amount.

 Patients aged 69 years or younger	 Patients aged 70 years or older
<ul style="list-style-type: none"> <li>● Copayments were 21,000 yen or more at each of several medical institutions during the same month. ➡Page 26</li> <li>● A family member enrolled in the same health insurance (same household) had copayments of at least 21,000 yen per month ➡Page 27</li> <li>● "Eligibility Certificate for Ceiling-Amount Application" was not presented at the payment counter ➡Page 28</li> <li>● You received a drug at a dispensing pharmacy ➡Page 29</li> </ul>	<ul style="list-style-type: none"> <li>● Copayments were made at each of several medical institutions during the same month. ➡Page 26</li> <li>● A family member enrolled in the same health insurance (same household) had copayments ➡Page 27</li> <li>● "Eligibility Certificate for Ceiling-Amount Application" was not presented at the payment counter* ➡Page 28</li> <li>● You received a drug at a dispensing pharmacy ➡Page 29</li> </ul>

\*For people 70 years or older with an application category of "Active income earner level III" or "General", it is not necessary to receive or present the "Eligibility Certificate for Ceiling-Amount Application" at the payment counter.



# Medical expense subsidy system for designated intractable diseases

## What is a designated intractable disease?

The following are the characteristics of an intractable disease:

- (1) The mechanism of onset is not clear.
- (2) There is no established treatment method.
- (3) It is a rare disease.
- (4) It requires long-term medical care.

Among intractable diseases, those that meet criteria specified by the government are referred to as designated intractable diseases.

If you are diagnosed with a specified intractable disease, part of the medical expenses for the treatment of the disease will be subsidized.

## If you have eosinophilic rhinosinusitis, you may be eligible for a medical subsidy

Eosinophilic rhinosinusitis is designated as an intractable disease, and patients who meet certain criteria can receive medical subsidies.



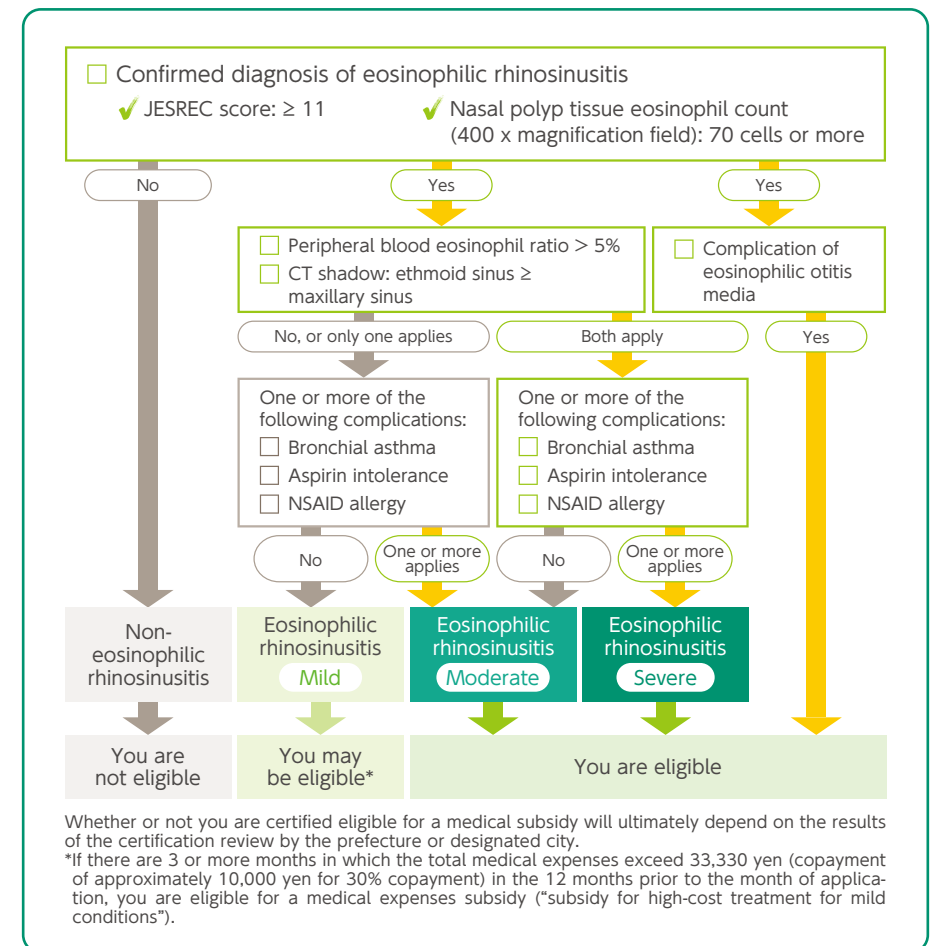
# Medical expense subsidy system for designated intractable diseases – Patients to whom it applies

The medical subsidy program for designated intractable diseases is applicable to any of the following patients.

**Among patients with a confirmed diagnosis of eosinophilic rhinosinusitis:**

- (1) Patients with moderate or severe symptoms
- (2) Patients with the complication of eosinophilic otitis media
- (3) Patients with mild symptoms who need to continue receiving high-cost medical care (Patients with mild symptoms are eligible if their medical care costs are high)

Please check with your doctor to find out which of the following conditions are present in your case.



Whether or not you are certified eligible for a medical subsidy will ultimately depend on the results of the certification review by the prefecture or designated city.

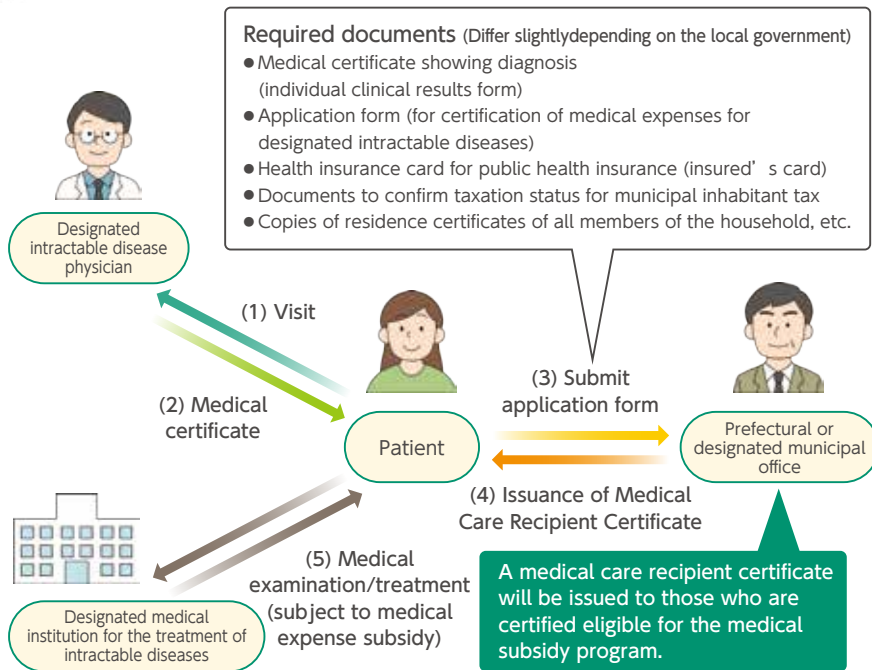
\*If there are 3 or more months in which the total medical expenses exceed 33,330 yen (copayment of approximately 10,000 yen for 30% copayment) in the 12 months prior to the month of application, you are eligible for a medical expenses subsidy ("subsidy for high-cost treatment for mild conditions").

# Medical expense subsidy system for designated intractable diseases [To receive subsidy]

To receive subsidies for medical expenses, you need to apply to your prefecture or designated city in advance to receive certification. To apply, you will need a medical certificate showing that you have been diagnosed with a designated intractable disease.

Once you are certified, a medical care recipient certificate will be issued. When you visit a medical institution for designated intractable diseases specified by the prefecture or designated city, you can use the subsidy system if you present the medical care recipient certificate.

## Flow chart of subsidy system



- Certification has an expiration date.
- If you still wish to receive the subsidy after the expiration date, you will need to apply for renewal every year.

For details of the application method, necessary documents, etc., please ask at the service counter of your prefectural or designated city office.

# Medical expense subsidy system for designated intractable diseases [Amount of copayment]

If you use the medical expense subsidy system, your copayment for medical expenses will be 20%\*.

In addition, the monthly ceiling amount for your copayment is determined according to your household income, and you do not need to pay more than the ceiling amount.

If you continue high-cost medical care for a long time (high-cost and long-term), the ceiling amount for your copayments will become even lower.

\*Please also refer to page 20 for age-based copayment ratios.

## Ceiling amount (monthly amount)

(Unit: yen)

Income Bracket	Classification Criteria (The figures in parentheses represent the approximate annual income for 2-member households (husband and wife))		Maximum amount of copayment (outpatient + inpatient) (patient copayment ratio: 20%)		
			General	High cost and long term**	Ventilator, etc.
Livelihood protection	—		0	0	0
Low income I	Municipal inhabitant's tax Not imposed (Household)	Employee's annual income Up to 800,000 yen	2,500	2,500	
Low income II		Employee's annual income More than 800,000 yen	5,000	5,000	
General income I	Municipal inhabitant's tax Less than 71,000 yen (About 1.6 million to 3.7 million yen)		10,000	5,000	1,000
General income II	Municipal inhabitant's tax 71,000 yen to not more than 251,000 yen (About 3.7 million to 8.1 million yen)		20,000	10,000	
Upper income	Municipal inhabitant's tax: 251,000 yen or more (About 8.1 million yen or more)		30,000	20,000	
Food cost at hospital admission			Patient pays full amount		

\*\*High-cost and long-term treatment benefit is applicable if there are 6 or more months in a year where the total medical expenses for treatment of certified intractable diseases exceed 50,000 yen.

# Medical expense subsidy system for designated intractable diseases [Copayment ceiling amount management]

For the treatment of designated intractable diseases, you may visit multiple medical institutions or receive drugs at dispensing pharmacies outside the hospital. **However, medical expenses can be subsidized only when you are treated for designated intractable diseases at medical institutions (hospitals/clinics, pharmacies, visiting nursing stations) that have been designated beforehand by the prefectural government, etc.**

If you visit multiple hospitals or receive drugs at dispensing pharmacies outside the hospital, then even if the copayment at one medical institution does not exceed the ceiling limit, you will still be eligible for the medical subsidy system if the total of copayments at all of the medical institutions you visited exceeds the ceiling amount. For this reason, the amounts of copayments must be recorded and managed in the "Copayment Ceiling Amount Management Form" that is issued with the medical care recipient certificate.


When you pay medical expenses at a medical institution, the medical institution will enter the total amount of medical expenses and the amount of copayment in the form. If the total amount reaches your ceiling amount, you will not need to make any more copayment that month.

Copayment Ceiling Amount Management Form for February 2025					
Name of examinee	○○△△		Examinee number	0012345	
Monthly ceiling amount:			10,000 yen		
Date	Name of designated medical institution	Total medical expenses (100% of expenses)	Amount of copayment	Cumulative amount of copayment (Monthly amount)	Collection seal
February 1	○○○Hospital	30,000 yen	6,000 yen	6,000 yen	Seal
February 1	××Pharmacy	6,000 yen	1,200 yen	7,200 yen	Seal
February 20	○○○Hospital	25,000 yen	2,800 yen	10,000 yen	Seal
February 20	××Pharmacy	4,000 yen			
As shown above, the monthly ceiling amount has been reached.					
Date	Name of designated medical institution				Confirmation seal
February 20	○○○Hospital				Seal

\*The format of the Copayment Ceiling Amount Management Form differs depending on the

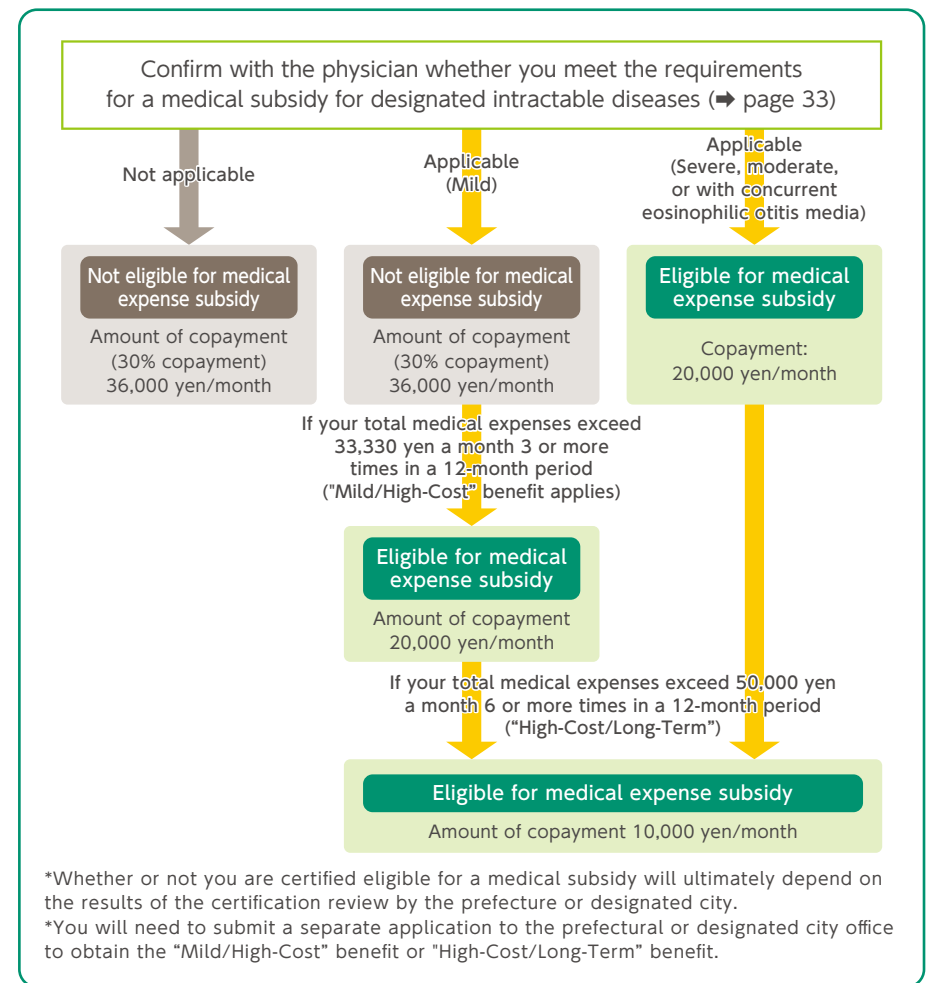
# Amount of copayment when using Dupixent® [model case]

Examples



Annual income  
4.5 million yen  
40 years old

Medical expenses (medical consultation fee + drug expenses)	120,000 yen
Amount of copayment (30% copayment)	36,000 yen
(20% copayment)	24,000 yen



\*Whether or not you are certified eligible for a medical subsidy will ultimately depend on the results of the certification review by the prefecture or designated city.  
\*You will need to submit a separate application to the prefectural or designated city office to obtain the "Mild/High-Cost" benefit or "High-Cost/Long-Term" benefit.

# Other subsidy systems to reduce your medical expense burden

## Additional benefit systems (systems unique to specific health insurance unions, etc.)

The high-cost medical care benefit system is a system established by the government, but depending on your medical insurance (insurer), you may receive a medical expense subsidy that is more than the amount specified by the government as a unique "additional benefit", and your ceiling amount may be set even lower.

Not all insurers use this system. For details, please contact your insurer (health insurance union, etc.).

## Medical expense subsidy system for students, etc.

Some schools, such as universities, operate a system to independently assist students in paying medical expenses. There may be a designated hospital, or procedures may be required. For details, please check with the Student Office, etc.

## Medical expense subsidy system for single parents

Some local governments provide medical subsidies to family members of single-parent households (mother and child and father and child). The contents of subsidy and application method differ among municipalities. For details, please check with the municipality in which you reside.

## Medical expenses deduction

If the total amount of medical expenses paid by family members who are in the same household exceeds 100,000 yen (5% of the total amount of income if the total amount of income is less than 2 million yen) in the year, you can receive a refund depending on income by receiving a medical expense deduction. To receive a medical expense deduction, you need to file a tax return.

Be sure to keep receipts issued by the medical institution.

### ● Calculation formula for medical expenses deduction

$$\begin{array}{|c|} \hline \text{Amount of} \\ \text{medical} \\ \text{expenses} \\ \text{deduction} \\ \text{(Up to} \\ \text{2 million yen)} \\ \hline \end{array} = \begin{array}{|c|} \hline \text{Total of} \\ \text{medical} \\ \text{expenses} \\ \text{actually paid} \\ \hline \end{array} - \begin{array}{|c|} \hline \text{Amount} \\ \text{covered} \\ \text{by insurance} \\ \text{money, etc.} \\ \hline \end{array} - \begin{array}{|c|} \hline \text{100,000 yen*} \\ \hline \end{array}$$

\*5% of the total income if the total income is less than 2 million yen

### ● Approximate refund

$$\begin{array}{|c|} \hline \text{Approximate tax refund} \\ \hline \end{array} = \begin{array}{|c|} \hline \text{Amount of} \\ \text{medical} \\ \text{expenses} \\ \text{deduction} \\ \hline \end{array} \times \begin{array}{|c|} \hline \text{Income} \\ \text{tax rate} \\ \hline \end{array}$$

➡ Contact: Nearest tax office