

Name of Hospital / Clinic

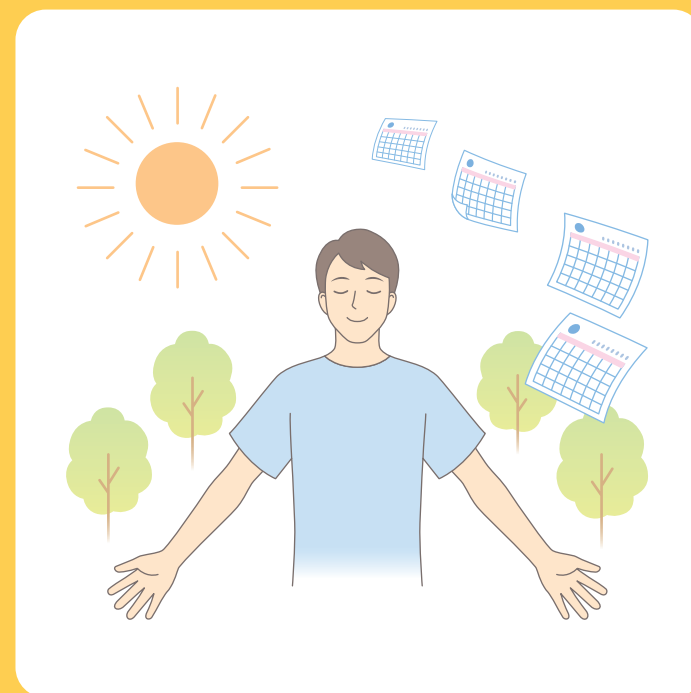
Sun Pharma Japan Ltd.

2021年9月作成  
ILM471HH1X

# Information About ILUMYA<sup>®</sup>

Supervisor

Atsuyuki Igarashi, Director of Department of Dermatology,  
NTT Medical Center Tokyo



Sun Pharma Japan Ltd.



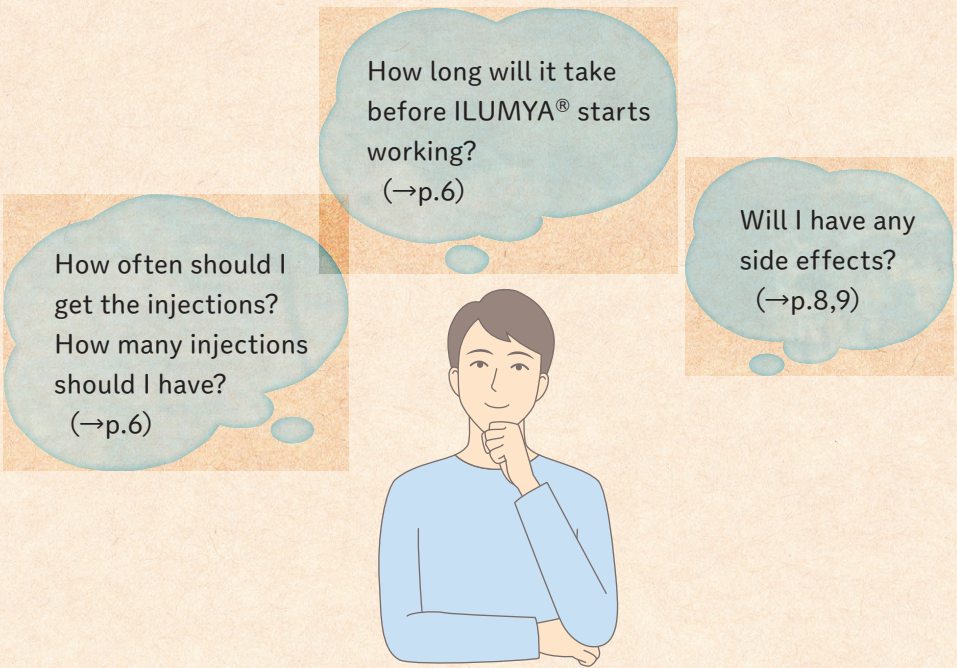
# For patients who start to treat with ILUMYA®

For treatment of psoriasis, in addition to ointments, oral medicines, and phototherapy (ultraviolet therapy), injectable agents called biologics have been used since 2010.

As biologics have been developed, now the goal of the psoriasis treatment is shifting from improving the symptoms to aiming for the disappearance of cutaneous symptoms and the daily activities not limited by the psoriasis symptoms.

ILUMYA® is one of the biologics.

Patients who are going to start the treatment may be feeling anxious and concerned about that. This brochure explains the treatment with ILUMYA®. We would appreciate it if you could proceed with the treatment aiming for your treatment goal.



## Contents

- Psoriasis treatment and biologics ..... 3
- Action of ILUMYA® ..... 4
  - It selectively inhibits a protein (IL-23) related to psoriasis onset.
- Please check before starting treatment ..... 5
- Dosing schedule for ILUMYA® ..... 6
  - You will receive five doses a year in the 1st year of the treatment and four doses a year from the 2nd year onwards (one dose requiring one injection).
- Precautions during the treatment ..... 7
- Major side effects of ILUMYA® ..... 8
  - If you notice something different from usual, please consult your doctor.
- Questions and answers about the treatment with ILUMYA® ..... 9
- ILUMYA® dosing management sheet ..... 11
- High-Cost Healthcare Benefit System (to reduce in the burden of treatment costs) ..... 13
- High-Cost Healthcare Benefit System (Applicable Multiple Payments) ..... 15
- An example of your copay amount when you receive the treatment with ILUMYA® ..... 16
- How to use the High-Cost Healthcare Benefit System ... 17





## Psoriasis treatment and biologics

Psoriasis is considered to occur when people with a predisposition to abnormalities in immune function have further various environmental factors (irregular lifestyles and diet, stress, obesity, infection, or specific drugs, etc.), which cause inflammation.

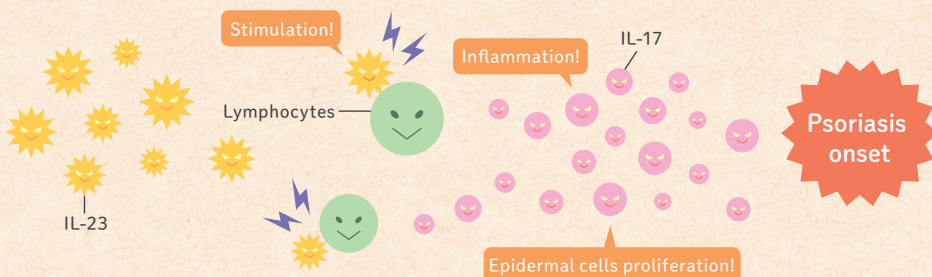
In general, psoriasis treatment starts by ointments and oral medicines to inhibit causal inflammation and the abnormal proliferation of skin cells, or by phototherapy (ultraviolet therapy) to enhance an improvement of symptoms.

However, patients with inadequate responses to these treatments are treated with biologics that are given as injections.

Biologics are drugs that selectively inhibit the actions of proteins (cytokines) relating to psoriasis onset and improve symptoms.

### Psoriasis onset and cytokine

- ① Interleukin 23 (IL-23), a cytokine, proliferates in an abnormal manner.
- ② IL-23 stimulates lymphocytes.
- ③ Stimulated lymphocytes produce pro-inflammatory cytokines (IL-17).
- ④ Inflammation occurs, leading to abnormal proliferation of epidermal cells of the skin.



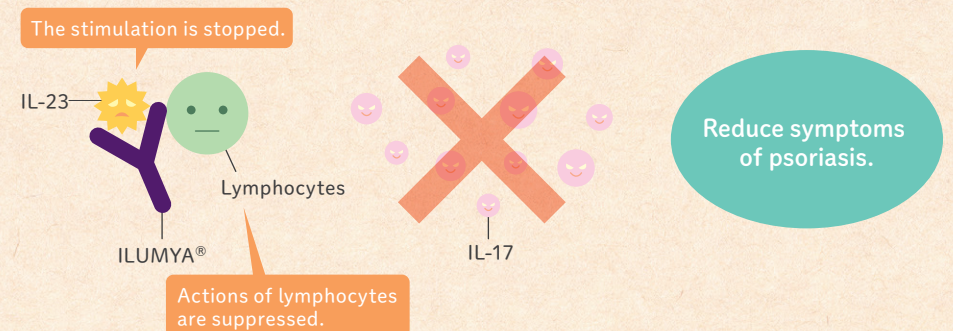
## Action of ILUMYA®

Major cytokines related to psoriasis onset are considered to be IL-23, TNF- $\alpha$ , and IL-17.

IL-23 stimulates lymphocytes to drive the production of IL-17; ILUMYA® is a biologics that inhibits the action of the abnormally proliferated IL-23 in patients with psoriasis. It reduces IL-17 production via lymphocytes, which improves the symptoms experienced on the skin.

### Action of ILUMYA®

- ① ILUMYA® inhibits IL-23 to stop stimulation of the lymphocytes.
- ② Actions of lymphocytes are suppressed, and pro-inflammatory cytokines (IL-17) become scarce.
- ③ The inflammation and the epidermal cell proliferation of the skin are inhibited.





## Please check before starting treatment

### ● You can receive the treatment with ILUMYA® if you

- ☒ have plaque psoriasis and have had inadequate responses to previous treatment (treatment with ointments, oral medicines, and ultraviolet therapy).

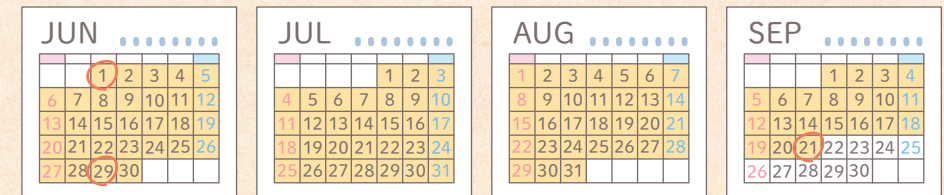
### ● Please contact your doctor before starting the treatment if you meet any of the following conditions:

- ☒ You have infection.  
(The treatment can worsen the infection.)
- ☒ You have a history of or are currently receiving treatment for tuberculosis.  
(The treatment can activate tuberculosis.)
- ☒ You are pregnant or possibly pregnant.  
(You cannot receive the treatment.)
- ☒ You are breastfeeding.  
(It is necessary to consider whether breastfeeding should be continued or stopped.)
- ☒ You have hypersensitivity to ILUMYA® ingredients.

## Dosing schedule for ILUMYA®

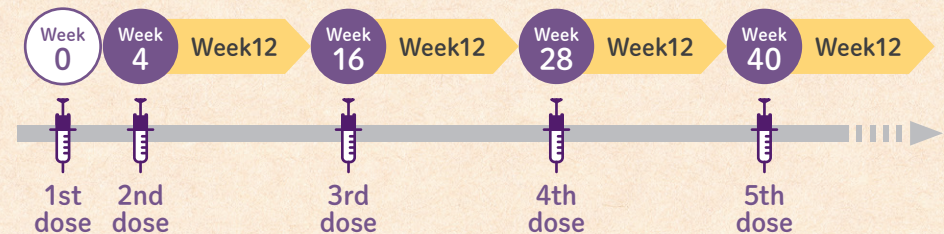
ILUMYA® is regularly administered by subcutaneous injection at medical facilities.

There is a difference depending on the person in how the effects will appear. Usually, we assess the treatment reactions within 16 weeks from the start of the treatment.



### Dosing schedule for ILUMYA®

You will receive five doses a year in the 1st year of the treatment and four doses a year from the 2nd year onwards (one dose requiring one injection).



### Sites for subcutaneous injection

Select a site with no psoriasis symptoms, such as your thighs, the abdomen, or the outer side of the upper arms, and administer an injection.



## Precautions during the treatment

Cytokines also have immune effects that protect your body; therefore, inhibition of the effects by ILUMYA® can make you more prone to bacterial or viral infection during the treatment. Please be careful of the following during the treatment with ILUMYA®.

### On the day of injection

- Do not stimulate the injected site.
- In some very rare circumstances, you can experience severe hypersensitivity (anaphylaxis); therefore, contact your doctor if you notice any symptoms of itching, urticaria, hoarse voice, sneezing, itchy throat, shortness of breath, or increases in heart rate.

### Daily life

- To prevent infection, wash your hands and gargle when returning home from being outdoors.

### Vaccinations

- To prevent influenza, it's desirable to get vaccinated before influenza viruses start to spread. For the vaccinations, please consult your doctor.
- Avoid the use of live vaccines (BCG, measles, rubella, mumps, chickenpox, etc.). When you need to get these vaccinations, please consult your doctor.

### Visiting other medical facilities and using other medicines

- When you visit other medical facilities or buy medicines at pharmacies, report that you are using ILUMYA®.

### Pregnancy and breastfeeding

- If you want to get pregnant or breastfeed, please contact your doctor.

## Major side effects of ILUMYA®

The treatment with ILUMYA® can cause side effects; however, it is not always true.

Please keep an eye on any changes in your physical condition; if you notice something different from usual, consult your doctor.

### Major side effects

- Infection



Fever, chilliness



Sore throat, headache



Sneezing, runny nose

- Injection site reaction



The injection site is red and painful.

### Side effects requiring special attention

- Serious infection



Fever



Coughing, shortness of breath



Feeling dull



# Questions and answers about the treatment with ILUMYA®

**Q** What should I do if I feel sick on the scheduled day of the ILUMYA® injection?

**A** Please contact your doctor and report your symptoms and when they started. Depending on the symptoms and the severity, the decision will be made whether to receive the treatment or not.

**Q** Can I take a bath on the day I receive the ILUMYA® injection?

**A** You can take a bath on the day of the injection, but please avoid stimulating your skin, such as rubbing the skin with nylon towels.

**Q** Do I always have side effects when I get an ILUMYA® injection?

**A** Side effects do not necessarily develop. ILUMYA® can make you more prone to infection like a cold; however, you can prevent them by being sure, on a routine basis, to wash your hands and gargle when returning home from being outdoors and do self-health management. Also, for side effects requiring special attention(p.8), if you notice them at an early stage and consult your doctor, you can safely continue the treatment.

**Q** How long should I continue the treatment with ILUMYA®?

**A** About how long to continue the treatment, contact your doctor.

When you stop the treatment, symptoms that are relieved by the treatment may recur. Do not stop treatment on your own. When you consider stopping the treatment, it is important to talk with your doctor thoroughly about the advantages and disadvantages before making a decision.

**Q** I take other drugs regularly and can I continue taking them while receiving the treatment with ILUMYA®?

**A** Before starting the treatment with ILUMYA®, be sure to tell your doctor and ask for instructions.

**Q** How much does the treatment with ILUMYA® cost?

**A** A patient's copay amount for the treatment will vary depending on the percentage of the patient's copayment for health insurance. If the amount paid at the cashier's windows of hospital / clinic or pharmacies, including medical expenses for the treatment with ILUMYA®, exceeds the fixed amount, the High-Cost Healthcare Benefit System(p.13-18) is applicable, which will reduce your burden.



# ILUMYA<sup>®</sup> dosing management sheet

Make notes of what you are worried about or you want to ask your doctor so that you will not forget them.

Dosing date    month    day

Please write down improved symptoms and symptoms you are worried about.

Circle the part where you got the injection.

Right

Left

Next scheduled dosing date    month    day

Dosing date    month    day

Please write down improved symptoms and symptoms you are worried about.

Circle the part where you got the injection.

Right

Left

Next scheduled dosing date    month    day

Dosing date    month    day

Please write down improved symptoms and symptoms you are worried about.

Circle the part where you got the injection.

Right

Left

Next scheduled dosing date    month    day

Dosing date    month    day

Please write down improved symptoms and symptoms you are worried about.

Circle the part where you got the injection.

Right

Left

Next scheduled dosing date    month    day

Dosing date    month    day

Please write down improved symptoms and symptoms you are worried about.

Circle the part where you got the injection.

Right

Left

Next scheduled dosing date    month    day

Dosing date    month    day

Please write down improved symptoms and symptoms you are worried about.

Circle the part where you got the injection.

Right

Left

Next scheduled dosing date    month    day

Dosing date    month    day

Please write down improved symptoms and symptoms you are worried about.

Circle the part where you got the injection.

Right

Left

Next scheduled dosing date    month    day

Dosing date    month    day

Please write down improved symptoms and symptoms you are worried about.

Circle the part where you got the injection.

Right

Left

Next scheduled dosing date    month    day

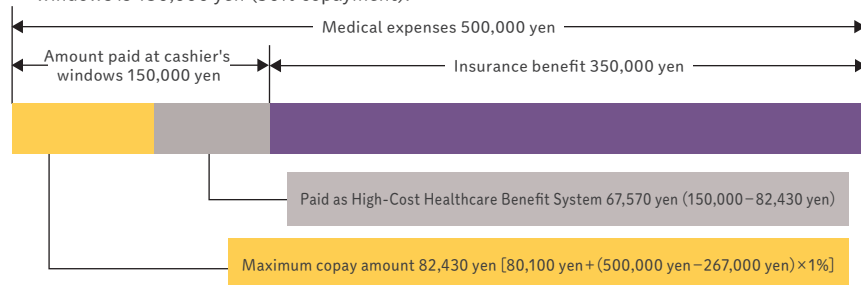


## High-Cost Healthcare Benefit System (to reduce in the burden of treatment costs)

If the amount paid at the cashier's windows of hospital / clinic or pharmacies exceeds the maximum amount of the copayment for a month (from the 1st day to the last day of a month), you will receive the payment for the amount in excess. It is called the High-Cost Healthcare Benefit System. The maximum copay amount will vary depending on your age and income(p.14). The High-Cost Healthcare Benefit System is a program stipulated by the Japanese government, which is available to anyone who enrolls in any public health insurance program.

### Example 1 32-year-old A with an annual income of about 3.7 million to about 7.7 million yen.

- In the case where the medical expense is 500,000 yen and the amount paid at the cashier's windows is 150,000 yen (30% copayment).

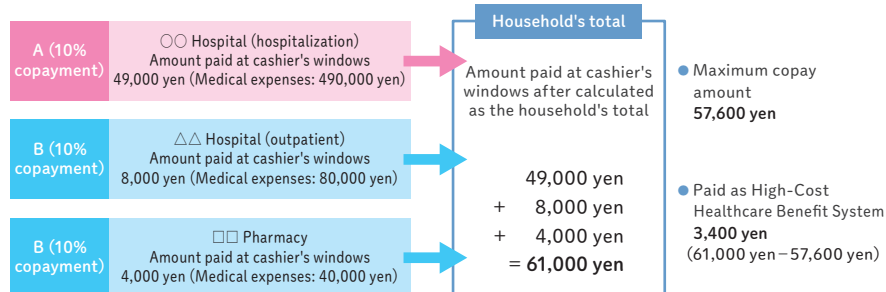


In addition, if the amount paid at the cashier's windows only once does not exceed the maximum copay amount, but the total amount of copayments for visiting medical facilities multiple times or the total amount of copayments for an entire household (limited to people having the same health insurance)\* exceeds the maximum copay amount, then it will be provided as the High-Cost Healthcare Benefit System (this is called the household total).

\*However, for people aged 69 or younger, only copayments of 21,000 yen or higher are totaled.

### Example 2 76-year-old A and 75-year-old B living in the same household with an annual income of 1.56 million to about 3.7 million yen.

- In the case where the medical expense is 610,000 yen for two people and the total amount paid at the cashier's windows is 61,000 yen (10% copayment for each).



### 69 years or younger: Maximum copay amount

Category		Maximum amount per month (per a household)
a)	An annual income of about 11.6 million yen or more Health insurance: Standard remuneration 830,000 yen or higher National health insurance: Former Stipulated Condition Income over 9.01 million yen	252,600 yen + (medical expenses - 842,000 yen) × 1%
b)	An annual income of about 7.7 million to about 11.6 million yen Health insurance: Standard remuneration 530,000 to 790,000 yen National health insurance: Former Stipulated Condition Income 6 million to 9.01 million yen	167,400 yen + (medical expenses - 558,000 yen) × 1%
c)	An annual income of about 3.7 million to about 7.7 million yen Health insurance: Standard remuneration 280,000 to 500,000 yen National health insurance: Former Stipulated Condition Income 2.1 million to 6 million yen	80,100 yen + (medical expenses - 267,000 yen) × 1%
d)	To an annual income of about 3.7 million yen Health insurance: Standard remuneration 260,000 yen or lower National health insurance: Former Stipulated Condition Income 2.1 million yen or lower	57,600 yen
e)	Resident tax-exempt person	35,400 yen

Note that even if the copayment paid at a single hospital / clinic (including the external prescription charge) does not exceed the maximum copay amount, you can combine your copayment amounts at other hospital / clinic in the same month (for people aged 69 or younger, the amount must be 21,000 yen or higher). When this total amount exceeds the maximum amount, you are eligible to receive the High-Cost Healthcare Benefit System.

### 70 years or older: Maximum copay amount

Category		Outpatient (per individual)	Maximum amount per month(per household)
The same level as working generation	An annual income of about 11.6 million yen or more Standard remuneration 830,000 yen or higher/ taxable income 6.9 million yen or higher		252,600 yen + (medical expenses - 842,000 yen) × 1%
	An annual income of about 7.7 million to about 11.6 million yen Standard remuneration 530,000 yen or higher/ taxable income 3.8 million yen or higher		167,400 yen + (medical expenses - 558,000 yen) × 1%
	An annual income of about 3.7 million to about 7.7 million yen Standard remuneration 280,000 yen or higher/ taxable income 1.45 million yen or higher		80,100 yen + (medical expenses - 267,000 yen) × 1%
Average level	An annual income of about 1.56 million to about 3.7 million yen Standard remuneration 260,000 yen or lower taxable income under 1.45 million yen	(18,000 yen) (144,000 yen per year)	57,600yen
Resident tax-exempt, etc.	II Resident tax-exempt household	8,000yen	24,600yen
	I Resident tax-exempt household (Pension income 800,000 yen or lower, etc.)		15,000yen

Note the even if the copayment paid at a single hospital / clinic (including the external prescription charge) does not exceed the maximum copay amount, you can combine your copayment amounts at other hospital / clinic in the same month. When this total amount exceeds the maximum amount, you are eligible to receive the High-Cost Healthcare Benefit System.

#### Additional Benefits

If you join a health insurance association of a corporation, or a mutual aid association, and your copayment exceeds the fixed amount, additional benefits may be available, where the amount in excess is paid as an additional amount. For more details, contact the support service of the public health insurance in which you are enrolled.



## Applicable Multiple Payments

### What are Applicable Multiple Payments?

It is a system that if you receive the High-Cost Healthcare Benefit System three or more times over within the last 12 months, the maximum copay amount of your copayment will be further reduced from the 4th payment.

#### ● 69 years or younger:

##### Maximum copay amount from the 4th payment onwards

Income categories	From the 4th payment onwards
People with an annual income of about 11.6 million yen or higher	140,100 yen
People with an annual income of about 7.7 million to about 11.6 million yen	93,000 yen
People with an annual income of about 3.7 million to about 7.7 million yen	44,400 yen
To an annual income of about 3.7 million yen	44,400 yen
Resident tax-exempt person	24,600 yen

#### ● 70 years or older:

##### Maximum copay amount from the 4th payment onwards

Income categories	From the 4th payment onwards
People with an annual income of about 11.6 million yen or higher	140,100 yen
People with an annual income of about 7.7 million to about 11.6 million yen	93,000 yen
People with an annual income of about 3.7 million to about 7.7 million yen	44,400 yen
To an annual income of about 3.7 million yen	44,400 yen

Note that for people who are classified into the resident tax-exempt, the Applicable Multiple Payments is not applicable.

How to apply will vary depending on the health insurance in which you are enrolled.  
For more details, contact the support service of your health insurance(p.18).

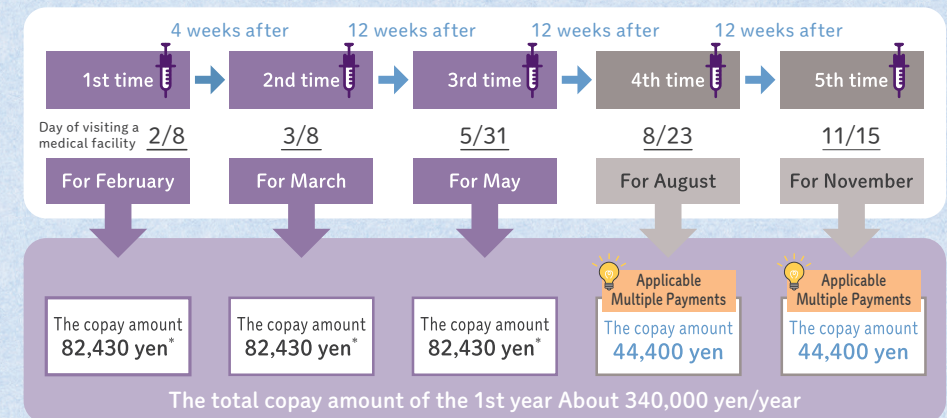
## An example of copay amount when you receive the treatment with ILUMYA®



Example: In the case of A (32 years old): An annual income of about 3.7 to about 7.7 million yen

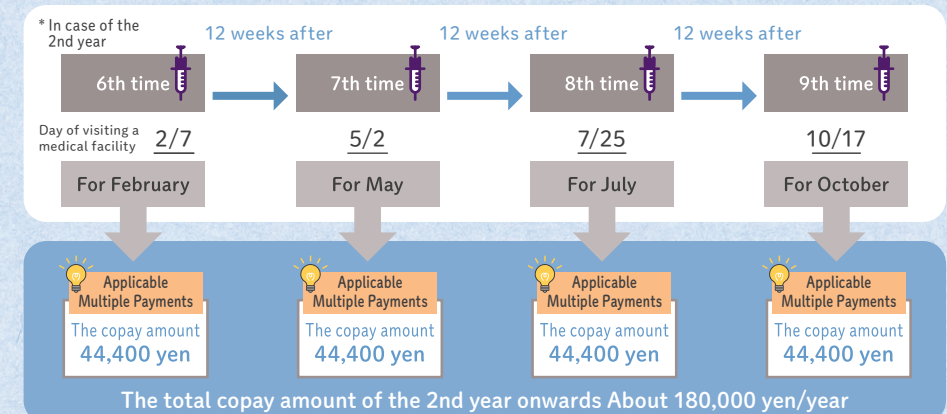
In the case where your medical expenses for visiting medical facilities once is 500,000 yen\*, the amount paid at the cashier's windows is 150,000 yen (30% copayment), and you use the High-Cost Healthcare Benefit System.

### The 1st year



\*Up to the 3rd time in the 1st year, the copay amount may increase or decrease depending on the tests conducted.

### From the 2nd year onwards



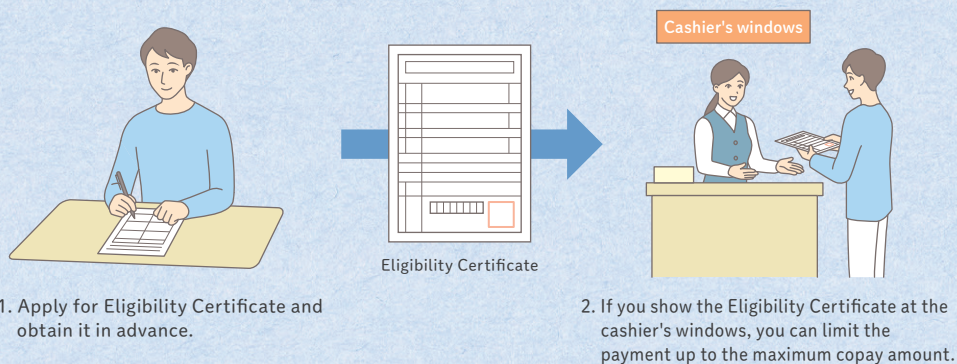


# How to use the High-Cost Healthcare Benefit System

You can use High-Cost Healthcare Benefit System according to the following methods.

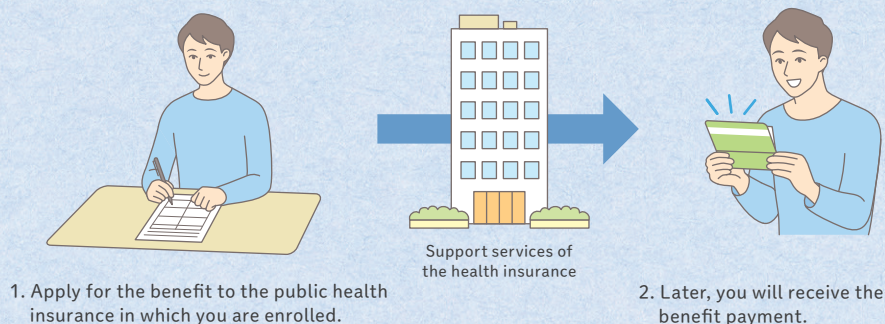
## ① Limit the amount paid at cashier's windows up to the maximum copay amount by using Eligibility Certificate.

If you receive an Eligibility Certificate for Maximum Copay Amount Application or Eligibility Certificate for Maximum Copay Amount Application and Reduction of the Standard Copayment Amount from your public health insurance where you are enrolled and show them when you pay, then you can limit the payment up to the maximum copay amount.



## ② Apply for the benefit after you paid at cashier's windows

By submitting or sending the application for payment of the High-Cost Healthcare Benefit System to your public health insurance where you are enrolled, you can receive the benefit payment (reimbursement). You will know which public health insurance you have by checking the front of your health insurance card.



For more details about the High-Cost Healthcare Benefit System, check the website of the Ministry of Health, Labour and Welfare “For people who use the High-Cost Healthcare Benefit System” or contact the support service of the public health insurance in which you are enrolled.

Website of the Ministry of Health, Labour and Welfare “For people who use the High-Cost Healthcare Benefit System” (confirmed this website function correctly in August 2021)

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryoku/iryohoken/juuyou/kougakuiyou/index.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryoku/iryohoken/juuyou/kougakuiyou/index.html)

## Check your public health insurance in which you are enrolled

There are five types of public health insurance. You will know the public health insurance you are enrolled in by checking your health insurance card.

- National health insurance
- Japan Health Insurance Association (Japan Health Insurance Association-managed health insurance)
- Union-managed health insurance
- Mutual Aid Association
- Advanced elderly medical service system

The image shows a sample of a Japanese Health Insurance Card. It contains fields for personal information: Name (氏名), Date of Birth (生年月日), Gender (性別), Fiscal Year (課税年度), Insured Person's Name (被保険者氏名), Institution Name (事業所名称), Insurance Number (保険者番号), Insured Person's Name (保険者名称), and Insured Person's Address (保険者所在地). The Insurance Number field is highlighted with a red box.

## Support services (Support services of insurers)

- National health insurance, advanced elderly medical service system  
→ Public offices of municipalities, Association of Medical Care Services for Older Senior Citizens
- Japan Health Insurance Association  
→ Each prefectural subdivision of the association
- Union-managed health insurance, mutual aid association  
→ Health insurance in which you are enrolled, mutual aid association