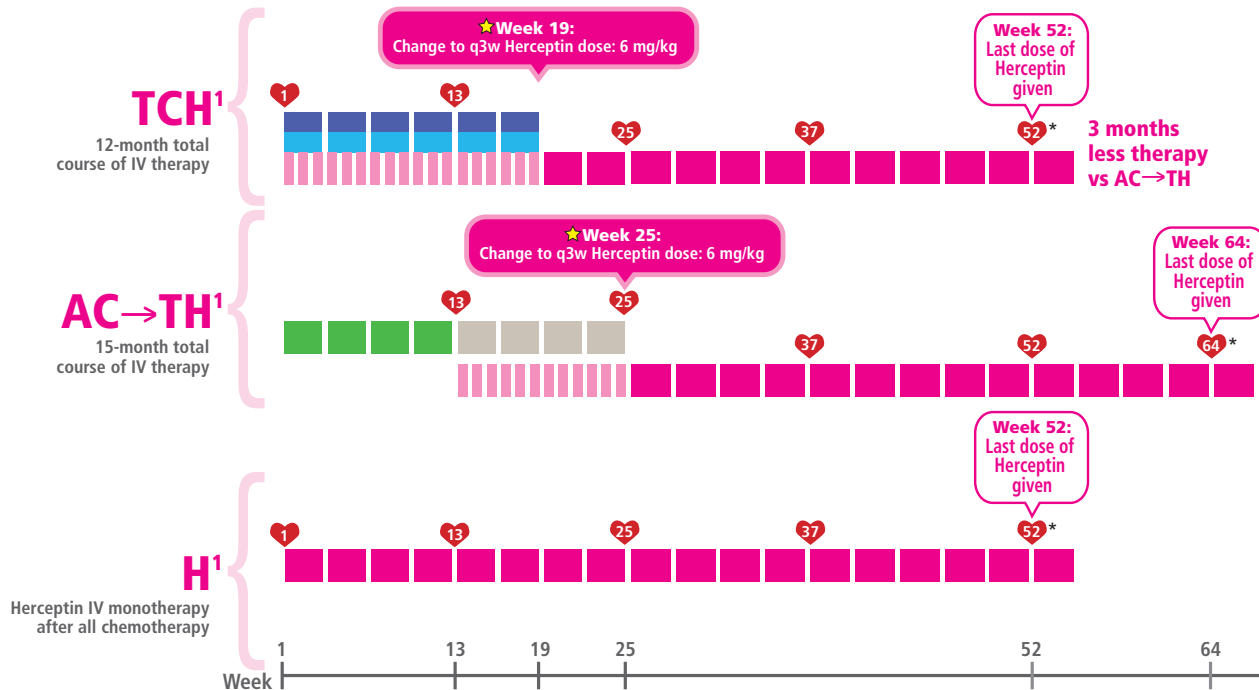


Herceptin dosing, administration, and cardiac monitoring in the adjuvant setting



Total Herceptin doses

	q1w	q3w
TCH	18	12
AC→TH	12	14
H	0	18

- **TCH (weeks 1-18):** 4 mg/kg loading dose, as a 90-minute infusion, at week 1; 2 mg/kg at weeks 2–18, as a 30-minute infusion, weekly for 17 weeks
- **TCH (weeks 19-52):** 6 mg/kg, as a 30–90-minute infusion, every 3 weeks for 12 cycles
- **AC→TH (weeks 13-24):** 4 mg/kg loading dose, as a 90-minute infusion, at week 13; 2 mg/kg at weeks 14–24, as a 30-minute infusion, weekly for 11 weeks
- **AC→TH (weeks 25-64):** 6 mg/kg, as a 30–90-minute infusion, every 3 weeks for 14 cycles
- **Herceptin monotherapy (weeks 1-52):** after completion of all chemotherapy regimens, 8 mg/kg loading dose, as a 90-minute infusion, at week 1; 6 mg/kg at weeks 4–52, as a 30–90-minute infusion, every 3 weeks for 18 cycles

- **Taxotere®† (docetaxel):** 75 mg/m² every 3 weeks for 6 cycles
- **Carboplatin:** at a target AUC of 6 mg/mL•min, as a 30- to 60-minute infusion, every 3 weeks for 6 cycles
- **AC:** doxorubicin 60 mg/m² and cyclophosphamide 600 mg/m² every 3 weeks for 4 cycles
- **T:** Taxane, either:
 - Taxotere 100 mg/m², every 3 weeks for 4 cycles, or
 - paclitaxel 175 mg/m², every 3 weeks for 4 cycles, or 80 mg/m² weekly for 12 weeks

Radiation therapy and/or hormonal therapy may be given after completion of chemotherapy if indicated.

*Left ventricular ejection fraction (LVEF) should be measured at baseline immediately prior to initiation of Herceptin, every 3 months during and upon completion of Herceptin, and every 6 months for at least 2 years following completion of Herceptin as a component of adjuvant therapy.¹

[†]Taxotere is a registered trademark of sanofi-aventis U.S. LLC.

★ **q3w Herceptin dose begins the week immediately following chemotherapy.**
 ♥ **Week of cardiac assessment**

Please see reverse side and accompanying full Prescribing Information for **Boxed WARNINGS** and additional important safety information.



Herceptin dosing and administration based on the BCIRG 006 trial

Summary of Herceptin dosing and administration guidelines¹

	Dosage	Infusion time
Loading dose	4 mg/kg	90 minutes
Subsequent doses during weekly administration <ul style="list-style-type: none">• For TCH regimen: through week 18• For AC→TH regimen: through week 12 of Herceptin (weeks 13–24 of total regimen)	2 mg/kg	30 minutes
Subsequent doses during q3w administration <ul style="list-style-type: none">• For TCH regimen: from week 19 through end of Herceptin therapy• For AC→TH regimen: from week 13 of Herceptin through end of Herceptin therapy (weeks 25–64 of total regimen)	6 mg/kg	30–90 minutes

Adjuvant indications

Herceptin is indicated for adjuvant treatment of HER2-overexpressing node-positive or node-negative (ER/PR-negative or with one high-risk feature) breast cancer:

- As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
- With docetaxel and carboplatin
- As a single agent following multi-modality anthracycline-based therapy

Please see accompanying full Prescribing Information for **Boxed WARNINGS** and additional important safety information.

Reference: 1. Herceptin Prescribing Information. Genentech, Inc. March 2009.

Boxed WARNINGS and Additional Important Safety Information

Cardiotoxicity and cardiac monitoring

- **Herceptin administration can result in sub-clinical and clinical cardiac failure manifesting as congestive heart failure (CHF) and decreased left ventricular ejection fraction (LVEF)**
 - The incidence and severity of left ventricular cardiac dysfunction was highest in patients who received Herceptin concurrently with anthracycline-containing chemotherapy regimens
 - Discontinue Herceptin treatment in patients receiving adjuvant therapy and strongly consider discontinuation of Herceptin in patients with metastatic breast cancer who develop a clinically significant decrease in left ventricular function
- Patients should undergo monitoring for decreased left ventricular function before Herceptin treatment, and frequently during and after Herceptin treatment
 - More frequent monitoring should be employed if Herceptin is withheld in patients who develop significant left ventricular cardiac dysfunction
- In one adjuvant clinical trial, cardiac ischemia or infarction occurred in the Herceptin-containing regimens

Infusion reactions, pulmonary toxicity, and neutropenia

- **Serious infusion reactions and pulmonary toxicity have occurred; fatal infusion reactions have been reported**
 - In most cases, symptoms occurred during or within 24 hours of administration of Herceptin
 - Herceptin infusion should be interrupted for patients experiencing dyspnea or clinically significant hypotension
 - Patients should be monitored until signs and symptoms completely resolve
 - Discontinue Herceptin for infusion reactions manifesting as anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome
- Exacerbation of chemotherapy-induced neutropenia has also occurred

Pregnancy category D

- Herceptin can cause oligohydramnios and fetal harm when administered to a pregnant woman

Most common adverse events

- The most common adverse reactions associated with Herceptin use were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, dyspnea, rash, neutropenia, anemia, and myalgia

www.herceptin.com

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 **Herceptin**
trastuzumab